SCHEDULE 2

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

Complex application

5. A complex application is an application, other than a major application, for a marketing authorization where the application falls within one or more of the following sub-paragraphs—

(a) the application relates to a medicinal product which is intended to be used in accordance with an indication for use in respect of a new category of patients or as treatment for a new category of disease;

(b) the application relates to a medicinal product containing a new combination of active ingredients that have not previously been included in that combination in a medicinal product in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(c) the application relates to a medicinal product containing a new excipient;

(d) the application relates to a medicinal product that is intended to be administered by a route of administration different from that used in relation to any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(e) the application relates to a medicinal product containing an active ingredient the manufacture of which involves a route of synthesis (or, in the case of a medicinal product not synthetically produced, a method of manufacture) different from that used in the manufacture of the active ingredient of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(f) the application relates to a medicinal product which is a controlled release preparation and is not a simple application;

(g) the application relates to a sterile medicinal product the manufacture of which involves a method of sterilisation different from that used in the manufacture of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(h) the application relates to a sterile medicinal product the container of which is directly in contact with the medicinal product and is made from different material from the container of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(i) unless a European Pharmacopoeia certificate of suitability covering the active ingredient has been submitted with the application, the application names as manufacturer of the active ingredient of the medicinal product in question a different manufacturer from the manufacturer of that active ingredient included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(j) the application relates to a medicinal product which is an influenza vaccine and in respect of which the manufacturer or the manufacturing process is different from that specified in any other marketing authorization which the applicant holds in respect of that product;

(k) the application is for the grant of a marketing authorization for a medicinal product which is an influenza vaccine, except where it relates only to an influenza vaccine containing a different strain or strains from that specified in any other marketing authorization which the applicant holds;

(l) the application is for the grant of a marketing authorization for a medicinal product which is to be delivered by way of a metered dose inhaler;

(m) the application is for the grant of a marketing authorization for a medicinal product which is in a powdered form and is to be delivered by way of inhalation;

(n) the application relates to a medicinal product—

(i) which is administered to the site of action or absorption by a method which has not previously been authorised in relation to any authorised medicinal product which contains the same active ingredient as the product in question; and

(ii) in respect of that other product, a marketing authorization (other than a product licence of right) has previously been granted;

(o) the application is an application for a marketing authorization to which Article 10(3) of the 2001 Directive applies;

(p) the application is an application where the sole or primary evidence for the safety and efficacy of the medicinal product consists of published scientific literature;

(q) the application is an extension application;

(r) the application—

(i) is not an application in accordance with Article 10, 10a or 10c of the 2001 Directive; and

(ii) includes the results of pre-clinical tests or clinical trials as specified in Article 8(3)(i) of the 2001 Directive; or

(s) the application is an application for a marketing authorization to which the first sub-paragraph of paragraph 3 of Part II of Annex I to the 2001 Directive applies.