SCHEDULE 1 Regulations 4(a) and 7(a)

CAPITAL FEES FOR APPLICATIONS FOR, AND VARIATIONS TO, LICENCES AND CERTIFICATES

PART I

INTERPRETATION

1. In this Schedule—

"active ingredient" means an ingredient of a medicinal product in respect of which therapeutic efficacy is claimed;

"complex application" means an application, other than a major application, for a product licence or, as the case may be, for a variation to a product licence where the application falls within one or more of the descriptions specified in sub-paragraphs (a) to (n) below:—

(a) the application is subject to the procedure laid down in Article 9 of Council Directive 75/ 319/EEC(**1**);

(b) 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;

(c) 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 product licence (other than a product licence of right) has previously been granted in the United Kingdom;

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

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

(f) 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 product licence (other than a product licence of right) has previously been granted in the United Kingdom;

(g) the application relates to a medicinal product which is a controlled release preparation except where—

(i) the application is for a variation in connection with such preparation and does not relate to a matter mentioned in sub-paragraph (b), (c), (d), (f), (j), (k) or (n) of this definition or where the variation applied for does not affect the usage or formulation of the product; or

(ii) the application is a simple application;

(h) 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

(**1**) O.J. No. L 147, 9.6.1975, p.13, as amended by Article 3 of Council Directive 83/570/EEC, O.J. No. L 332, 28.11.1983, p.1.

product which contains the same active ingredient as the product in question and in respect of which a product licence (other than a product licence of right) has previously been granted in the United Kingdom;

(i) 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 product licence (other than a product licence of right) has previously been granted in the United Kingdom;

(j) the application is an application to vary a product licence (parallel import) to include—

(i) importation of the same medicinal product bearing a marketing authorization issued in a different Member State of the European Economic Community; or

(ii) importation of a medicinal product which is differently formulated from any other medicinal product in respect of which a product licence (parallel import) has previously been granted in the United Kingdom;

(k) 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 product licence (other than a product licence of right) has previously been granted in the United Kingdom;

(l) 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 product licence which the applicant holds in respect of that product;

(m) the application is for the grant of a product licence 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 product licence which the applicant holds; or

(n) the application is to vary a product licence and relates to a change in the formulation of the medicinal product comprising one or more of the following—

(i) a change in the quantity of that product's active ingredient;

(ii) a change which necessitates in-vivo bioavailability studies to be performed on that product;

(iii) a change in that product's preservative system; or

(iv) a change in two or more of that product's excipients other than to colours, or substances which are present only in trace amounts in the finished product.

"major application" means an application for a product licence in respect of a medicinal product containing a new active ingredient;

"new active ingredient" means an active ingredient that has not previously been included as an active ingredient in a medicinal product in respect of which a product licence (other than a product licence of right) has previously been granted in the United Kingdom;

"new excipient" means any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product—

(a) which is intended to be administered by the same route of administration as the product in question; and

(b) in respect of which a product licence (other than a product licence of right) has previously been granted in the United Kingdom, except that, in the case of a medicinal product intended to be administered orally, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation) as an approved ingredient or additive in food or in a food product;

"simple application" means an application for a product licence to which Article 4.8(a)(i) of Council Directive 65/65/EEC(**2**) applies other than one for a product licence for a medicinal product which is a new strength of a product in respect of which a product licence has previously been granted in the United Kingdom;

"standard application" means any application which is not a major, complex or simple application or an application for a product licence (parallel import).

PART II

CAPITAL FEES FOR APPLICATIONS FOR LICENCES AND CERTIFICATES

Product licences

1. Subject to paragraphs 2, 3, 4 and 5, the fee payable under regulation 4(a) in connection with an application for a product licence of a kind described in Column 1 of the following Table shall be the fee specified in the corresponding entry in Column 2 of that Table:

TABLE

Column 1 Kind of Application	Column 2 Fee Payable
1. Major application	
(a) in respect of any such application—	
	(a) (a) £17,000
(i) to which paragraph 5 of Chapter III of Part 3 of the Annex to Council Directive 75/318/EEC(**3**) applies; or	
(ii) which relates to an article or substance in relation to which Part II of the Act has effect by virtue of an order made under section 104 or 105(1)(a) of the Act;	
(b) (b) in any other case	(b) (b) £92,000
2. Complex application	**2.** £17,000
3. Standard application	**3.** £7,000
4. Simple application	**4.** £2,000
5. Application for a product licence (parallel import)	**5.** £1,750

2. Notwithstanding the provisions of paragraph 1, in the case of an article or substance to which Part II of the Act applies by virtue of the Medicines (Surgical Materials) Order 1971(**4**), the fee payable under regulation 4(a) in connection with an application for a product licence shall be £250.

3. Where a major application is made by a person who is already the holder of a clinical trial certificate in respect of a medicinal product containing the same active ingredient as the medicinal product in respect of which the product licence is applied for, the fee payable under regulation 4(a) in connection with that application shall be reduced by the amount of the fee paid in connection with the application for that certificate.

(**2**) O.J. No. 22, 9.2.1965, p.369/65, as amended by Article 1.1 of Council Directive 87/21/EEC, O.J. No.L15/36, 17.1.1987.
(**3**) O.J. No. L147, 9.6. 1975, p 1.
(**4**) S.I. 1971/1267.

4.—(1) In this paragraph—

"joint development" means the development by two or more applicants for product licences relating to medicinal products—

(a) each of which contains the same new active ingredient or combination of new active ingredients but with different proprietary names and which does not require separate consideration by a committee established under section 4 of the Act or by the Medicines Commission; and

(b) the development of which has been notified to the licensing authority at or before the time the application is submitted, as being a joint development undertaken by those applicants; and

(c) in respect of which applications for product licences have been received by the licensing authority within one month of each other;

"primary applicant" means that party to a joint development who first makes an application for a product licence relating to a new active ingredient which was the subject of that joint development; and

"secondary applicant" means any party to a joint development, other than the primary applicant, who makes an application for a product licence relating to the same new active ingredient as that which was the subject of the application made by the primary applicant.

(2) Where a joint development relates to a medicinal product and an application for a product licence is submitted to the licensing authority by a secondary applicant, the fee payable under regulation 4(a) shall be—

(a) in respect of the first or only product licence applied for by that secondary applicant, the amount payable in respect of a complex application under paragraph 1 above;

(b) in respect of each additional product licence applied for by that secondary applicant relating to that medicinal product which is of the same dosage form, the amount payable in respect of a standard application under paragraph 1 above;

(c) in respect of the first additional product licence applied for by that secondary applicant relating to that medicinal product which is of a different dosage form, the amount payable in respect of a complex application under paragraph 1 above, and in respect of any other such application by that secondary applicant, the amount payable in respect of a standard application under paragraph 1 above.

5.—(1) Subject to sub-paragraphs (2) and (3), where an application for a product licence (except an application by a secondary applicant within the meaning of paragraph 4) is for more than one such licence each relating to a medicinal product containing the same active ingredient or combination of ingredients, the fee payable under regulation 4(a) shall be of an amount equal to the aggregate of the amounts payable under paragraph 1 above in respect of a separate application for each such licence.

(2) If the application is a major application, the amount payable shall be the amount payable in respect of a major application under paragraph 1 above plus—

(a) in respect of each additional product licence applied for which relates to a medicinal product of a different dosage form, the amount payable in respect of a complex application under paragraph 1 above; and

(b) in respect of each additional product licence applied for which relates to a medicinal product of the same dosage form but of a different strength of active ingredient or different combination of active ingredients, the amount payable in respect of a standard application under paragraph 1.

(3) If the application is a complex application, the amount payable shall be the amount payable in respect of a complex application under paragraph 1 above plus—

(a) in respect of each additional product licence applied for which relates to a medicinal product of a different dosage form, the amount payable in respect of a complex application under paragraph 1 above; and

(b) in respect of each additional product licence applied for which relates to a medicinal product of the same dosage form but of a different strength of active ingredient or different combination of active ingredients, the amount payable in respect of a standard application under paragraph 1 above.

Manufacturers' licences

6.—(1) The fee payable under regulation 4(a) in connection with an application for a manufacturer's licence shall be—

(a) in a case to which sub-paragraph (2) applies, £80;

(b) in any other case, £1,400.

(2) This sub-paragraph applies to the case of an application for a manufacturer's licence which is limited solely to the manufacture or assembly of medicinal products, the sale or supply of which do not require a product licence and to which Article 2(2)(i)(e) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(**5**) applies.

Wholesale dealers' licences

7.—(1) Subject to sub-paragraph (2), the fee payable under regulation 4(a) in connection with an application for a wholesale dealer's licence shall be £750.

(2) The fee payable under regulation 4(a) shall be £400 where an application for a wholesale dealer's licence relates to anything done in a registered pharmacy by or under the supervision of a pharmacist and amounts to wholesale dealing, where such dealing constitutes no more than 15% of the total turnover of the sale of licensed medicinal products carried on at that pharmacy.

(3) For the purposes of sub-paragraph (2) above, turnover shall be calculated in accordance with the provisions of Part II of Schedule 3.

Clinical trial certificates

8. The fee payable under regulation 4(a) in connection with an application for a clinical trial certificate shall be £17,000.

PART III

CAPITAL FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES AND CERTIFICATES

Product licences

1. Subject to paragraphs 2, 3, 4, 11 and 12, the fee payable under regulation 7(a) in connection with an application for variation of a product licence shall be—

(a) in the case of any complex application, £8,500; and

(b) in any other case, £280.

(**5**) S.I. 1971/1450.

2. Where a product licence has been granted in accordance with an application to which paragraph 5 of Chapter III of Part 3 of the Annex to Council Directive 75/318/EEC applies, the fee in connection with the first application for variation of that product licence made within 5 years of the date of the grant of that product licence, so as to authorise use of the medicinal product in a new therapeutic area, shall, in addition to the fee payable under regulation 7(a), be the difference between the fee paid in connection with the application for the grant of that licence and the fee which would have been payable had that application been a major application and the provisions of that paragraph had not applied.

3. The fee payable under regulation 7(a) in connection with an application for variation of a product licence (parallel import) which is a complex application, shall be the same as that payable in connection with an application for the grant of such a licence as specified in paragraph 1 of Part II of this Schedule.

4. The fee payable under regulation 7(a) in connection with an application for variation of a product licence shall be £80 in respect of each variation applied for which falls within one of the following paragraphs—

(a) a change of either or both of the name and the address of the holder of the licence;

(b) a change of either or both of the name and the address of a manufacturer, assembler, storer or distributor named in the licence where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise and any change of address does not involve a change of the site of manufacture, assembly or storage or from which distribution takes place;

(c) the removal from the licence of details of one or more sites of manufacture, assembly or storage or from which distribution takes place;

(d) the removal from the licence of details of any of the activities to which the licence relates;

(e) the removal from the licence of details of any of the indications authorised for administration of the medicinal product;

(f) n relation to a product licence (parallel import), the removal from the licence of details of any of the medicinal products which the holder of the licence is authorised to import.

Manufacturers' licences

5. Subject to paragraphs 6 and 11, the fee payable under regulation 7(a) in connection with an application for variation of a manufacturer’s licence shall be—

(a) in the case of a manufacturer’s licence referred to in paragraph 6(2) of Part II of this Schedule, £80; and

(b) in any other case, £200.

6. The fee payable under regulation 7(a) in connection with an application for variation of a manufacturer’s licence shall be £80 in respect of each variation applied for which consists of a change to the licence not requiring an inspection or medical, scientific or pharmaceutical assessment.

Wholesale dealers' licences

7. Subject to paragraphs 8 and 11, the fee payable under regulation 7(a) in connection with an application for variation of a wholesale dealer’s licence shall be £200.

8. The fee payable under regulation 7(a) in connection with an application for variation of a wholesale dealer’s licence shall be £80 in respect of each variation applied for which consists of a change to the licence not requiring an inspection or medical, scientific or pharmaceutical assessment.

Clinical trial certificates

9. Subject to paragraphs 10 and 11, the fee payable under regulation 7(a) in connection with an application for variation of a clinical trial certificate shall be £280.

10. Where an application is made for a variation to a provision of a clinical trial certificate and the variation applied for consists of no more than a change of either or both the name and address of the holder of the certificate, the fee payable under regulation 7(a) shall be £80.

Identical variations

11. Subject to paragraph 12 below, where more than one application is made at the same time by the same applicant for the variation of a product licence, a manufacturer's licence, a wholesale dealer's licence or a clinical trial certificate and where the applications are for identical variations, the fee payable under regulation 7(a)—

(a) in connection with the first application considered by the licensing authority shall be the appropriate amount specified in this Part of this Schedule;

(b) in connection with each of the other applications shall be 50% of that amount.

12. Where more than one complex application is made at the same time by the same applicant for the variation of a product licence, the fee payable under regulation 7(a)—

(a) in connection with the first application considered by the licensing authority shall be the appropriate amount specified in this Part of this Schedule;

(b) in connection with each of the other applications where the applications are for identical variations and in respect of which no further medical, scientific or pharmaceutical assessment is required shall be the amount which would be payable if the application was not a complex application.