SCHEDULE 1

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

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—	
(i) to which paragraph 5 of Chapter III of Part 3 of the Annex to Council Directive 75/318/EEC(**1**) applies; or	(a) (a) £17,000
(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(**2**), 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.

4.—(1) In this paragraph—

(**1**) O.J. No. L147, 9.6. 1975, p 1.
(**2**) S.I. 1971/1267.

"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(**3**) 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.

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