SCHEDULE 3

PERIODIC FEES FOR LICENCES

PART III

PERIODIC FEES FOR MARKETING AUTHORIZATIONS AND LICENCES

Marketing authorizations

1. Subject to paragraphs 2 to 6 inclusive, the fee payable under regulation 14(3) in connection with the holding of a marketing authorization relating to a medicinal product of a kind described in Column 1 of the following Table shall be the appropriate fee specified in the corresponding entry in Column 2 of that Table.

TABLE

Column 1 Kind of product	Column 2 Fee payable
1. New Active Substance	**1.** £11,900
2. Other kinds of Medicinal Product—	(a) (a) £5,950
(a) Any product (not being a derivative of a new active substance) in respect of which a marketing authorization has been granted in consequence of a complex application submitted on or after 1st April 1989	
(b) (b) Prescription Only Medicine (i) Standard Fee	(b) (i) £1,075
(ii) Reduced Rate Fee	(b) (ii) £535
(iii) Maintenance Fee	(b) (iii) £180
(c) (c) Pharmacy Medicine (i) Standard Fee	(c) (i) £535
(ii) Reduced Rate Fee	(c) (ii) £270
(iii) Maintenance Fee	(c) (iii) £120
(d) (d) General Sale List Medicine (i) Standard Fee	(d) (i) £240
(ii) Reduced Rate Fee	(d) (ii) £120
(iii) Maintenance Fee	(d) (iii) £90
(e) (e) Herbal Remedy	(e) (e) £60
(f) (f) Homoeopathic Medicinal Product or Authroposophic Product	(f) (f) £30

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(**1**), the fees payable under regulation 14(3) in connection with the holding of a marketing authorization or licence shall, where appropriate, be—

(a) a standard fee of £300;

(b) a reduced rate fee of £145; or

(c) a maintenance fee of £95.

3. Subject to paragraph 4, where a marketing authorization is held in respect of a derivative of a new active substance, the fee payable under regulation 14(3) shall be—

(a) where it is of the same dosage form as, but of a different strength of active ingredient or different combination of active ingredients from, that relating to the new active substance, £3,575;

(b) where it is of a different dosage form from that relating to the new active substance, £5,950.

4.—(1) The appropriate fee specified in the Table in paragraph 1 as being that payable in connection with the holding of a marketing authorization relating to a new active substance shall be payable only for the five consecutive relevant fee periods following the fee period during which that marketing authorization was granted, or if the authorization was granted before 18th July 1991,—

(a) where that authorization was granted before 1st April 1991, until and including the relevant fee period during which falls the fifth anniversary of the granting of the authorization; and

(b) where that authorization was granted on or after 1st April 1991, until and including the relevant fee period during which falls the fourth anniversary of the granting of the authorization.

(2) Subject to sub-paragraphs (3) and (5), the appropriate periodic fee in respect of a derivative of a new active substance shall be payable for the five relevant fee periods following the fee period during which the marketing authorization relating to the new active substance upon which the application was based, was first granted, or if the authorization was granted before 18th July 1991,—

(a) where that authorization was granted before 1st April 1991, until and including the relevant fee period during which falls the fifth anniversary of the granting of the authorization; and

(b) where that authorization was granted on or after 1st April 1991, until and including the relevant fee period during which falls the fourth anniversary of the granting of the authorization.

(3) The fee payable in accordance with entry 2(a) of the Table set out in paragraph 1 shall only be payable for the three relevant fee periods following the year beginning 1st April during which the marketing authorization was granted.

(4) Where a marketing authorization is surrendered and at the same time another marketing authorization held by the authorization holder is varied so as to include in that other authorization the provisions of the first authorization—

(a) where the first authorization relates to a new active substance, the fee payable shall, for each fee period mentioned in sub-paragraph (1), be that specified at entry 1 of the Table set out in paragraph 1;

(b) in all other cases, the fee payable shall, for each fee period mentioned in sub-paragraph (3), be that specified at entry 2(a) of that Table.

(**1**) S.I.1971/1267.

(5) In respect of fee periods following those referred to in sub-paragraphs (1), (2) and (3) of this paragraph the periodic fees shall be the appropriate fees for the kind of medicinal product in question specified in entries 2(b), (c) or (d) of the Table set out in paragraph 1.

(6) In connection with the holding of a marketing authorization in respect of a limited use drug or a derivative of a limited use drug the periodic fee shall be—

(a) where turnover exceeds £200 000, that which would be payable if the drug were, respectively. a new active substance or a derivative of a new active substance;

(b) where turnover does not exceed £200,000, that payable in respect of a prescription only medicine in accordance with entry 2(b)(i) of the Table set out in paragraph 1.

5. Where a marketing authorization relates to any two or more of the kinds of medicinal product described in entries 2(b), (c) or (d) of the Table in paragraph 1, the fee payable under regulation 14(3) shall be in accordance with the lower of the fees specified as corresponding to those entries in Column 2 of that Table.

6. Where a reduced rate fee or a maintenance fee may be payable in respect of any relevant fee period and an authorization holder does not submit evidence of turnover in relation to the relevant calendar year to the satisfaction of the licensing authority, the periodic fee payable by him shall, where applicable, be the standard fee for each description of medicinal product in respect of which a marketing authorization is held by the authorization holder.

Manufacturer's licences

7. The fee payable under regulation 14(3) in connection with the holding of a manufacturer's licence shall be £235.

Wholesale dealer's licences

8.—(1) Subject to sub-paragraph (2) and to paragraph 9, the fee payable under regulation 14(3) in connection with the holding of a wholesale dealer's licence shall be £145.

(2) The fee payable under regulation 14(3) shall be £90 where—

(a) the 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 authorised medicinal products carried on at that pharmacy or, where the licence does not relate to anything done in a registered pharmacy, where the total turnover of the sale by way of wholesale dealing in authorised medicinal products does not exceed £30,000; or

(b) the wholesale dealer's licence relates to general sale list medicines only.

9. Where in respect of any relevant fee period, the holder of a wholesale dealer's licence does not submit evidence of turnover in relation to the relevant calendar year to the satisfaction of the licensing authority, the periodic fee payable by him shall be the fee prescribed in paragraph 8(1).