

SCHEDULE 3

PERIODIC FEES FOR LICENCES

PART III

PERIODIC FEES FOR LICENCES

Product licences

1.—(1) Subject to paragraphs 2 to 6 inclusive, the fee payable under regulation 14(3) in connection with the holding of a product licence relating to a medicinal product 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.

(2) Where Column 1 of the following Table or paragraph 2 refers to a standard fee, a reduced rate fee or a maintenance fee, the fee specified in the corresponding entry in Column 2 of that Table or in that paragraph shall be payable in the circumstances specified in Part I of this Schedule.

TABLE

Column 1 Kind of Product	Column 2 Fee Payable
1. New Active Substance	1. £10,000
2. Other kinds of Medicinal Product	(a) (a) £5,000
(a) Any product (not being a derivative of a new active substance) in respect of which a licence has been granted in consequence of a complex application submitted on or after 1st April 1989	
(b) (b) Prescription Only Medicine	(b) (i) £900
(i) Standard Fee	
(ii) Reduced Rate Fee	(b) (ii) £450
(iii) Maintenance Fee	(b) (iii) £150
(c) (c) Pharmacy Medicine	(c) (i) £450
(i) Standard Fee	
(ii) Reduced Rate Fee	(c) (ii) £225
(iii) Maintenance Fee	(c) (iii) £100
(d) (d) General Sales List Medicine	(d) (i) £200
(i) Standard Fee	
(ii) Reduced Rate Fee	(d) (ii) £100
(iii) Maintenance Fee	(d) (iii) £75
(e) (e) Herbal Product	(e) (e) £50

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Column 1 Kind of Product	Column 2 Fee Payable
(f) (f) omoeopathic Product and Anthroposophic Product	(f) (f) £25

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⁾ or the Medicines (Specified Articles and Substances) Order 1976⁽²⁾, the fees payable under regulation 14(3) in connection with the holding of a product licence shall, where appropriate be—

- (a) a standard fee of £250;
- (b) a reduced rate fee of £125; or
- (c) a maintenance fee of £80.

3. Subject to paragraph 4 below, where a licence 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 than, that relating to the new active substance, £3,000;
- (b) where it is of a different dosage form to the new active substance, £5,000;

4.—(1) The appropriate fee specified in the Table in paragraph 1 as being that payable in connection with the holding of a product licence relating to a new active substance shall be payable only for the five relevant licence fee periods following the licence fee period during which that licence was granted, or if the licence was granted before these Regulations came into force, until and including the relevant licence fee period during which falls the fifth anniversary of the date of granting of the licence.

(2) Subject to sub-paragraphs (3) and (5) below, the appropriate periodic fee in respect of a derivative of a new active substance shall be payable for the five relevant licence fee periods following the licence fee period during which the product licence relating to the new active substance upon which the application was based, was first granted, or if the licence was granted before these Regulations came into force, until and including the relevant licence fee period during which falls the fifth anniversary of the date of granting of the licence.

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

(4) Where a licence in respect of which a fee is payable in accordance with entry 2(a) of the Table in paragraph 1 is surrendered and at the same time another licence held by the licence holder is varied so as to include in that other licence the provisions of the first licence, then the fee payable in respect of that other licence shall, for the period mentioned in paragraph 3, be that specified at entry 2(a) of that Table instead of any other fee.

(5) In respect of licence fee periods following those referred to in sub-paragraphs (1), (2) and (3) of this paragraph, periodic fees shall be payable in accordance with entries 2(b), (c) or (d) of the Table set out in paragraph 1.

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

(1) [S.I. 1971/1267](#).

(2) [S.I. 1976/968](#).

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- (a) subject to paragraph 4(1) 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 the Table set out in paragraph 1.

5. Where a product licence 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 above, 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 licence fee period and a licence 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 product licence is held by the licence holder.

Manufacturers' licences

7. The fee payable under regulation 14(3) in connection with the holding of a manufacturer's licence shall be £200.

Wholesale dealers' 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 £125.

(2) The fee payable under regulation 14(3) shall be £75 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 licensed medicinal products carried on that pharmacy; or
- (b) the wholesale dealer's licence relates to general sales list medicines only.

9. Where in respect of any relevant licence 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) above.