SCHEDULE 3 Regulation 14

PERIODIC FEES FOR LICENCES

PART I

INTERPRETATION

1. In this Schedule

"anthroposophic product" means a medicinal product prepared in accordance with the methods of anthroposophic medicine which is or supplied as an anthroposophic product and is so described by the person who sells or supplies that medicinal product;

"complex application" has the same meaning as in Schedule 1 except that it relates only to an application for a product licence;

"derivative", in relation to a limited use drug or a new active substance, means a medicinal product—

(a) which contains the same active ingredient or combination of active ingredients as that drug or substance but which either—

(i) is a different dosage form of that drug or substance, or

(ii) is of the same dosage form as, but of a different strength of active ingredient to, or of a different combination of active ingredients to, that drug or substance; and

(b) in respect of which an application for a product licence was made before the determination of the application for the product licence for that drug or substance;

"general sales list medicine" means a medicinal product (not being an anthroposophic product, a herbal product or a homoeopathic product) of a description or falling within a class specified in an Order made under section 51(1) of the Act;

"herbal product" means a medicinal product which is a herbal remedy as defined in section 132(1) of the Act;

"homoeopathic product" means a medicinal product prepared in accordance with the methods of homoeopathic medicine or similar methods which is sold or supplied as a homoeopathic product and is so described by the person who sells or supplies that medicinal product;

"limited use drug" means a medicinal product in respect of which an application for a product licence has been submitted, to which paragraph 5 of Chapter III of Part 3 of the Annex to the Council Directive 75/318/EEC applies;

"maintenance fee" means the periodic fee payable where the licence holder has notified the licensing authority that the medicinal product to which the product licence relates, being a prescription only medicine, a pharmacy medicine or a general sales list medicine, is not expected either to be manufactured anywhere under the terms of that product licence, or to be imported into the United Kingdom during the relevant licence fee period; and

(a) that during the period of 15 months preceding the commencement of the relevant licence fee period the medicinal product has not been either manufactured anywhere under the terms of that product licence, or imported into the United Kingdom; or

(b) where the medicinal product had been either manufactured anywhere under the terms of that product licence, or imported into the United Kingdom during the period referred to in (a) above, that turnover did not exceed £1,000 during the relevant calendar year;

"new active substance" means a medicinal product which is not a limited use drug and which contains an active ingredient which 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 been granted in the United Kingdom—

(a) in the five years preceding the coming into force of these Regulations; or

(b) in the five years preceding 31st December in the licence fee period preceding the relevant licence fee period.

"pharmacy medicine" means a medicinal product (not being an anthroposophic product, a herbal product or a homoeopathic product) which is neither a prescription only medicine nor a general sales list medicine;

"prescription only medicine" means a medicinal product (not being an anthroposophic product, a herbal product, a homoeopathic product, a new active substance or a derivative of a new active substance) of a description or falling within a class specified in an order made under section 58(1) of the Act;

"reduced rate fee" means the periodic fee payable where the turnover relating to a medicinal product, being a prescription only medicine, a pharmacy medicine or a general sales list medicine, does not exceed £30,000 in the relevant calendar year;

"standard fee" means the periodic fee payable where the turnover relating to a medicinal product, being a prescription only medicine, a pharmacy medicine or a general sales list medicine, does exceed £30,000 in the relevant calendar year;

"turnover" means the amount calculated in accordance with paragraphs 1 and 2 of Part II of this Schedule.

PART II

CALCULATION OF TURNOVER

1.—(1) Subject to sub-paragraph (2) below, "turnover" means, for the purposes of calculating the periodic fee payable in connection with the holding of a licence for a relevant licence fee period, the gross value at manufacturer's prices of all medicinal products to which the licence relates which are sold or supplied in the United Kingdom by the holder of the licence during the year which ends on the 31st December preceding the beginning of that licence fee period.

(2) For the purposes of calculating the periodic fee payable in connection with the holding of licences mentioned in Part IV of this Schedule for a relevant licence fee period, the quantity of products taken for the purposes of sub-paragraph (1) above is the aggregate of all the products to which the licences relate.

2. For the purposes of paragraph 1, manufacturer's prices are the following—

(a) for products sold or supplied by the licence holder to wholesalers or to distributors or assemblers named in the licence, which he has manufactured or obtained from the manufacturer, the prices charged for the supply;

(b) for products sold or supplied by the licence holder to retailers, which he has manufactured or obtained from the manufacturer, the prices so charged for the supply less an amount which, in the opinion of the licensing authority, represents the difference between those prices and the prices which would have been charged, in accordance with the practice prevailing during the relevant year, by a wholesaler for the product;

(c) for products sold or supplied by the licence holder which he has neither manufactured nor obtained from the manufacturer, the price which he paid for the supply.

3.—(1) For the purpose of satisfying the licensing authority for the purposes of Part III of this Schedule, an applicant shall, if requested, state the amount of the turnover, calculated in accordance with the preceding paragraphs of this Part of this Schedule.

(2) Where the licence holder fails to furnish evidence of the amount of annual turnover to the satisfaction of the licensing authority, the licensing authority may require the licence holder to furnish an auditor's certificate containing such evidence.

(3) If within one month of the date by which such certificate is required to be furnished, or such longer period as the licensing authority may allow, the licence holder has failed to furnish it, the periodic fee for the relevant licence fee period shall be that provided for in paragraphs 6 and 9 of Part III of this Schedule or such lesser sum as the licensing authority may specify in a notice served on the licence holder.

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 (i) Standard Fee	(b) (i) £900
(ii) Reduced Rate Fee	(b) (ii) £450
(iii) Maintenance Fee	(b) (iii) £150
(c) (c) Pharmacy Medicine (i) Standard Fee	(c) (i) £450
(ii) Reduced Rate Fee	(c) (ii) £225
(iii) Maintenance Fee	(c) (iii) £100

Column 1 Kind of Product	Column 2 Fee Payable
(d) (d) General Sales List Medicine (i) Standard Fee	(d) (i) £200
(ii) Reduced Rate Fee	(d) (ii) £100
(iii) Maintenance Fee	(d) (iii) £75
(e) (e) Herbal Product	(e) (e) £50
(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, fo rthe period mentioned in paragraph 3, be that specified at entry 2(a) of that Table instead of any other fee.

(**1**) S.I. 1971/1267.
(**2**) S.I. 1976/968.

(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–

(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 pharmist 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.

PART IV

TYPES OF PRODUCT LICENCE FOR WHICH ONLY ONE PERIODIC FEE IS PAYABLE

1. Product licences (parallel import) held by the same person each of which is subject to the condition that its continuing validity is dependent on the continuing validity of another product licence which is the same licence in each case.

2. Licences held in respect of homoeopathic or anthroposophic products which are two or more attenuations of the same mother tincture or other solution of the same trituration.