SCHEDULE 3 Regulation 14(2) and (3)

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 sold 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; "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 is either

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

(ii) 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 marketing authorization was made before the determination of the application for the marketing authorization for that drug or substance;

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

"herbal remedy" has the same meaning as in section 132(1) (general interpretation provisions) of the Act;

"homoeopathic medicinal product" means any medicinal product (which may contain a number of principles) prepared from products, substances or compositions called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member State;

"limited use drug" means a medicinal product in respect of which an application for a marketing authorization has been submitted, to which Section G of Part 4 of the Annex to Council Directive 75/318/EEC applies;

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

(a) that the medicinal product has not been manufactured or imported into the United Kingdom during the period of 12 months preceding the commencement of the relevant fee period; or

(b) where the medicinal product had been manufactured 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 marketing authorization (other than a product licence of right) has been granted in the five years preceding 31st December in the fee period preceding the relevant fee period;

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

"prescription only medicine" means a medicinal product (not being an anthroposophic product, a herbal remedy, 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) (medicinal products on prescription only) 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 sale 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 sale list medicine, does exceed £30,000 in the relevant calendar year;

"turnover" means the amount calculated in accordance with Part II of this Schedule.

PART II

CALCULATION OF TURNOVER

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

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

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

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

(b) for products sold or supplied by the authorization 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 authorization 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 authorization holder fails to furnish evidence of the amount of annual turnover to the satisfaction of the licensing authority, the licensing authority may require the authorization 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 authorization holder has failed to furnish such certificate, the sum payable by way of periodic fees for the relevant fee period in question shall be equal to the fee provided for in paragraphs 6 and 9 of Part III of this Schedule or shall be such lesser sum as the licensing authority may specify in a written notice served on the authorization holder.

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

Column 1 Kind of product	Column 2 Fee payable
(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—

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

(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.

(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).

PART IV

TYPES OF MARKETING AUTHORIZATION FOR WHICH ONLY ONE PERIODIC FEE IS PAYABLE

1. Marketing authorizations (parallel import) in respect of which separate marketing authorizations have been granted pursuant to the provisions of Council Directive 65/65/EEC(**2**) in two or more member States of the European Community, which have no differences having therapeutic effect, from a medicinal product in respect of which a single marketing authorization has previously been granted in the United Kingdom.

2. Marketing authorizations held in respect of homoeopathic medicinal products or anthroposophic products which are—

(a) two or more attenuations of the same mother tincture or other solution of the same trituration; or

(b) two or more attenuations of a particular combination of mother tinctures, other solutions or triturations.

(**2**) OJNo. L22, 9.2.65, p. 369/65. The Directive was amended by Directives 75/319/EEC (OJ No. L147, 9.6.75, p.13); 83/570/EEC (OJ No. L332, 28.11.83, p. 1); 87/21/EEC (OJ No. L15, 17.1.87, p. 36); 89/341/EEC (OJ No. L142, 25.5.89, p.11); 89/343/EEC (OJ No. L142, 25.5.89, p. 16) and 93/39/EEC (OJ No. L214, 24.8.93, p. 22).