SCHEDULE 3 Regulation 33(2) and (3), 34(2)

PERIODIC FEES FOR LICENCES

PART 1

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;

"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;

"limited use drug" means a medicinal product in respect of which an application for a marketing authorization has been submitted, to which point 6 of Part II of Annex I to the 2001 Directive applies or which is in respect of an orphan medicinal product;

"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 that period;

"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 £35,000 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 £35,000 in the relevant calendar year; and

"turnover" means the amount calculated in accordance with Part 2 of this Schedule.

PART 2

Calculation of Turnover

Calculation of turnover

2.—(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 period of 12 months preceding the commencement of the relevant fee period.

(2) For the purposes of calculating the periodic fee payable in connection with the holding of marketing authorizations mentioned in Part 4 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.

Manufacturer's prices

3. For the purposes of paragraph 2, 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 that holder 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 that holder 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; or

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

Evidence of turnover

4.—(1) For the purpose of satisfying the licensing authority for the purposes of Part 3 of this Schedule, an applicant shall, if requested, state the amount of the turnover, calculated in accordance with paragraphs 2 and 3.

(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 10 and 13 of Part 3 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 3

Periodic Fees for Marketing Authorizations and Licences

Marketing authorizations

5. Unless paragraphs 6 to 10 apply, the fee payable under regulation 33(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 is the applicable fee specified in the corresponding entry in column 2 of that table.

Periodic fees for holding marketing authorization

Column 1 *Kind of product*	*Column 2* *Fee payable*
1. New Active Substance	£23,025
2. Other kinds of Medicinal Product—	
(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	£9,481
(b) Prescription Only Medicine	
(i) Standard Fee	£2,371
(ii) Reduced Rate Fee	£1,183
(iii) Maintenance Fee	£384
(c) Pharmacy Medicine	
(i) Standard Fee	£1,038
(ii) Reduced Rate Fee	£519
(iii) Maintenance Fee	£192
(d) General Sale List Medicine	
(i) Standard Fee	£429
(ii) Reduced Rate Fee	£213
(iii) Maintenance Fee	£93
(e) Herbal Remedy	£113
(f) National homoeopathic product	£81

Column 1	*Column 2*
Kind of product	*Fee payable*
(g) Homoeopathic or anthroposophic product which is the subject of a licence of right	£74

Marketing authorization: where Part 2 of the Act applies

6. 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 fee payable under regulation 33(3) in connection with the holding of a marketing authorization or licence is—

(a) £527, in the case of a standard fee;

(b) £260, in the case of a reduced rate fee; or

(c) £110, in the case of a maintenance fee.

Marketing authorization: derivatives

7. Unless paragraph 8 applies, where a marketing authorization is held in respect of a derivative of a new active substance, the fee payable under regulation 33(3) is—

(a) £9,481, where the medicinal product to which the authorization relates has a different route of administration from that of the new active substance; or

(b) £6,400, in any other case.

Number of fee periods

8.—(1) The fee specified in—

(a) paragraph 5 for a new active substance; and

(b) in paragraph 7 for a derivative of a new active substance,

is only payable for the five relevant fee periods following that in which the marketing authorization is granted.

(2) The fee payable in accordance with entry 2(a) of the table set out in paragraph 5 is only payable for the three relevant fee periods following the year beginning 1st April during which the marketing authorization is granted.

(3) 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, the fee payable—

(a) for the five relevant fee periods following the fee period during which the marketing authorization is granted is the fee specified at entry 1 of the table set out in paragraph 5, where the first authorization relates to a new active substance;

(b) in all other cases, for each fee period mentioned in sub-paragraph (2), is the fee specified at entry 2(a) of that table.

(4) In respect of fee periods following those referred to in sub-paragraphs (1) to (3) of this paragraph, the periodic fees are 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 5.

(**1**) S.I. 1971/1267; Part II of the Act is applied by Article 3 of the Order which has been amended by S.I. 1994/3119, 2004/1031 and 2006/2407.

(5) In connection with the holding of a marketing authorization in respect of a limited use drug or a derivative of a limited use drug—

(a) where turnover exceeds £200,000, until the expiry of the five relevant fee periods following the fee period during which the marketing authorization was granted, the periodic fee payable is the fee that 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 or where a periodic fee has been payable in respect of the limited use drug or derivative of a limited use drug for five relevant fee periods following the fee period during which the marketing authorization was granted, the periodic fee payable is the fee payable in respect of a prescription only medicine in accordance with entry 2(b)(i) of the table set out in paragraph 5.

Authorisation for two or more kinds of medicinal product

9. Where a marketing authorization relates to any two or more medicinal products of a kind described in entries 2(b), (c) or (d) of column 1 of the table in paragraph 5, the fee payable under regulation 33(3) shall be the lower of the fee specified as corresponding to those entries in column 2 of that table.

Reduced fees

10. 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 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 or manufacturing authorisations

11.—(1) Unless sub-paragraph (3) applies, the fee payable under regulation 33(3) in connection with the holding of a manufacturer's licence is £457.

(2) The fee payable under regulation 33(3) in connection with the holding of a manufacturing authorisation is £457.

(3) The fee payable under regulation 33(3) in connection with the holding of a manufacturer's licence which relates to the import of exempt imported products from a third country is the fee payable in accordance with sub-paragraph (1) and an additional amount calculated in accordance with paragraph 15.

Wholesale dealer's licences

12.—(1) Subject to sub-paragraph (2) and to paragraphs 13 and 16, the fee payable under regulation 33(3) in connection with the holding of a wholesale dealer's licence is £281.

(2) The fee payable under regulation 33(3) is £168 where the wholesale dealer's licence—

(a) 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;

(b) 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 £35,000; or

(c) relates to general sale list medicines only.

(3) For the purposes of sub-paragraph (2), the total turnover shall be calculated in accordance with Part 2 of this Schedule and the references to "marketing authorization" and "authorization holder" in Part 2 shall be construed as if they were references to "wholesale dealer's licence" and "licence holder", respectively.

Wholesale dealer's licences: evidence

13. 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 shall be the fee prescribed in paragraph 12(1).

Wholesale dealer's licences: exempt imported products

14. The fee payable under regulation 33(3) in connection with the holding of a wholesale dealer's licence which relates to exempt imported products is the fee payable in accordance with paragraphs 12 and 13 and an additional amount calculated in accordance with paragraph 15.

Additional amount for manufacturer's licences and wholesale dealer's licences which relate to exempt imported products

15.—(1) The additional amount referred to in paragraph 11(3) and 14 in relation to any fee period shall be the fee specified in the entry in column 2 of the following table corresponding to the estimated number of special import notices for that fee period specified in column 1.

Additional periodic fee in connection with exempt imported products

Column 1 *Number of special import notices*	*Column 2* *Additional amount*
1 to 20	£126
21 to 100	£505
101 to 1,000	£2,020
1,001 to 5,000	£10,100
5,001 to 20,000	£25,250
20,001 to 50,000	£50,500
50,001 to 100,000	£101,000
100,001 or more	£151,500

(2) For the purposes of this paragraph, the estimated number of special import notices for any fee period shall be the number notified in writing to the licence holder by the licensing authority before the start of that fee period as the number of such notices which the authority estimate will be given by the holder during the fee period.

Clinical trial authorisations

16. The fee payable under regulation 34(2) in connection with the holding of a clinical trial authorisation is £342.

Traditional herbal registrations

17. The fee payable under regulation 33(3) in connection with the holding of a traditional herbal registration is £96.

PART 4

Types of Marketing Authorization for which only One Periodic Fee is Payable

Specified parallel import licences

18. In a case where—

(a) parallel import licences in respect of medicinal products for which separate marketing authorizations have been granted pursuant to the provisions of the 2001 Directive in one or more Member States of the European Union; and

(b) those medicinal products have no differences in respect of therapeutic effect from a medicinal product in respect of which a single marketing authorization has previously been granted in the United Kingdom,

only one periodic fee relating to the medicinal product of the kind in question is payable.