STATUTORY INSTRUMENTS

1995 No. 1116

MEDICINES

The Medicines (Products for Human Use — Fees) Regulations 1995

Made - - - -	*20th April 1995*
Laid before Parliament	*20th April 1995*
Coming into force - -	*21st April 1995*

The Secretary of State concerned with health in England, the Secretaries of State concerned with health and with agriculture in Wales and in Scotland respectively, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, with the consent of the Treasury, in exercise of powers conferred upon them by section 1(1) and (2) of the Medicines Act 1971(**1**), or, as the case may be, those conferred by the said provisions and now vested in them(**2**) and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations(**3**), hereby make the following Regulations:

(**1**) 1971 c. 69, as amended by section 21 of the Health and Medicines Act 1988 (c. 49); by virtue of section 1(3) of the 1971 Act expressions in that section have the same meaning as in the Medicines Act 1968 (c. 67), as amended by the Transfer of Functions (Wales) Order 1969 (S.I.1969/388). The expression "the Ministers" is defined in section 1(1) of the 1968 Act as so amended. By virtue of regulation 9(12) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144), references in section 1(1) and (2)(b) to a licence under Part II of the 1971 Act include a reference to a marketing authorization under those Regulations.

(**2**) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969; in the case of the Secretary of State concerned with agriculture in Wales by virtue of article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272); in the case of the Northern Ireland Departments by Virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(**3**) See section 129(6) of the Medicines Act 1968 (c. 67) as extended to include regulations made under the Medicines Act 1971 by section 1(3)(b) of that latter Act.

PART I

GENERAL

Citation and commencement

1. These Regulations may be cited as the Medicines (Products for Human Use — Fees) Regulations 1995 and shall come into force on 21st April 1995.

Interpretation

2.—(1) In these Regulations, unless the context requires otherwise—

"the Act" means the Medicines Act 1968 and, except as provided below, expressions used in these Regulations have the same meaning as in the Act;

"the 1994 Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**4**);

"authorised medicinal product" means a medicinal product in respect of which either a marketing authorization or marketing authorization (parallel import) has been granted;

"blood product" means any medicinal product derived from human blood or human plasma and includes albumin, coagulating factor and immunoglobulin of human origin;

"capital fee" means any fee, other than a periodic fee, payable under the provisions of these Regulations;

"change of ownership application" means an application for a marketing authorization for a medicinal product in respect of which a person other than the applicant is the holder of a marketing authorization and which—

(a) includes a statement to the effect that that other person intends to cease selling or supplying that product pursuant to that authorization;

(b) is signed by or on behalf of that other person, as well as by or on behalf of the applicant; and

(c) except for the name and address of the applicant and particulars in relation to the labelling of the product and any leaflet relating to it, contains, or is accompanied by, particulars which are in all material respects identical to the particulars referred to in the marketing authorization already held by that other person;

"Community marketing authorization" means a marketing authorization granted by the European Commission under Council Regulation (EEC) No. 2309/93(**5**);

"fee period" means the period beginning with the first day of April in any year and ending with the last day of March in the following year;

"immunological product" means any medicinal product which is a vaccine, toxin, serum or allergen product;

"manufacturer's licence" means a manufacturer's licence which relates wholly or partly to medicinal products for human use;

"marketing authorization" means—

(a) a United Kingdom marketing authorization granted by the licensing authority under the 1994 Regulations;

(b) a Community marketing authorization; or

(**4**) S.I. 1994/3144.
(**5**) OJ No. L214, 24.8.93. p.1.

(c) a product licence, including one which is a licence of right or one which has effect as a marketing authorization by virtue of paragraph 1 of Schedule 6 (transitional provisions) to the 1994 Regulations;

which relates to a medicinal product for human use;

"marketing authorization (parallel import)" means a marketing authorization granted by the licensing authority in respect of a medicinal product which is imported into the United Kingdom from another member State of the European Community, in respect of which there has been granted a marketing authorization by another member State of the Community and which has no differences having therapeutic effect from a medicinal product in respect of which a marketing authorization has previously been granted in the United Kingdom;

"medicinal product" includes any medicinal product for human use to which Chapters II to V of Council Directive 65/65/EEC(**6**) apply and any substance or article specified in any order for the time being in force made under section 104 (application of the Act to certain articles and substances) or 105(1)(a) (application of the Act to certain other substances which are not medicinal products) of the Act which directs that Part II of the Act shall have effect in relation to such substance or article;

"periodic fee" means a fee payable under regulation 14;

"product licence of right" means a product licence within the meaning of section 7 (general provisions as to dealing with medicinal products) of the Act which is a licence of right within the meaning of section 25(4) (entitlement to licence of right) of the Act;

"relevant fee period" means any fee period during any part of which a marketing authorization or licence in respect of which a periodic fee is payable is in force;

"variation" in relation to—

(a) a United Kingdom marketing authorization granted by the licensing authority under the 1994 Regulations; or

(b) a product licence which has effect as such a marketing authorization by virtue of paragraph 1 of Schedule 6 (transitional provisions) to those Regulations;

means "variation to the terms of a marketing authorization" as defined in Article 2.1 of Commission Regulation (EC) No. 541/95(**7**);

"wholesale dealer's licence" means a wholesale dealer's licence which relates wholly or partly to medicinal products for human use;

and Part I of Schedule 1 shall have effect for the purpose of interpreting that Schedule.

(2) In these Regulations any reference to a regulation or a Schedule shall be construed as a reference to a regulation contained in these Regulations or, as the case may be, to a Schedule thereto; any reference in a regulation or a Schedule to a paragraph shall be construed as a reference to a paragraph of that regulation or, as the case may be, Schedule, and any reference in a paragraph to a sub-paragraph shall be construed as a reference to a sub-paragraph of that paragraph.

Fees payable in connection with applications and inspections

3.—(1) The amount of a capital fee payable in connection with an application is that payable in accordance with these Regulations as in force when the application is made.

(2) The amount of a fee payable in respect of an inspection is that payable in accordance with these Regulations as in force when the inspection is made.

(**6**) OJ No. 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).

(**7**) OJ No. L55, 11.3.95, p. 7.

PART II

CAPITAL FEES F0R APPLICATIONS FOR AUTHORIZATIONS, LICENCES OR CERTIFICATES AND FOR ASSOCIATED INSPECTIONS

Applications for authorizations, licences or certificates

4. Subject to regulations 5, 19 and 23, in connection with an application for a marketing authorization (other than a Community marketing authorization), a manufacturer's licence, a wholesale dealer's licence or a clinical trial certificate, there shall be payable by the applicant—

(a) the fee prescribed in Part II of Schedule 1 in connection with that application; and

(b) in respect of any inspection defined in paragraph 1 of Schedule 2 made in connection with that application the fee payable in accordance with paragraphs 2 to 6 of that Schedule.

Inspections in connection with multiple applications for authorizations or licences

5. Where an inspection mentioned in regulation 4(b) is made at a site which has been named as a possible site for manufacture or assembly of a medicinal product, or for the preparation of a substance which is to be used in the manufacture of an immunological product or a blood product, by more than one applicant for—

(a) a marketing authorization and that site is located outside the United Kingdom; or

(b) a manufacturer's licence and that site is located in the United Kingdom,

the fee in respect of that inspection shall be payable in equal proportions by each of those applicants.

Applications for certificates by exporters of medicinal products

6.—(1) In connection with an application for a certificate issued under section 50 (export certificates) of the Act, there shall be payable by the applicant—

(a) if the applicant requests that the certificate be issued within 24 hours of receipt of the application, a fee of £120:

(b) in any other case, a fee of £60; and

(c) in either case

(i) a fee of £60 for each set of certificates requested by the applicant in addition to one: and

(ii) a fee of £14 for each certified copy of the original certificate not forming part of a set of certificates, requested by the applicant.

(2) In paragraph (1)(c), "set of certificates" means—

(a) if it is the first set, the original certificate plus up to four certified copies of that certificate; and

(b) in any other case, up to five copies of that certificate.

PART III

CAPITAL FEES FOR APPLICATIONS FOR VARIATIONS OF AUTHORIZATIONS, LICENCES OR CERTIFICATES AND FOR ASSOCIATED INSPECTIONS

Variations of authorizations, licences and certificates

7.—(1) Subject to regulations 8, 9, 19 and 23, a person who makes an application—

(a) under regulation 4 of the 1994 Regulations for the variation of a United Kingdom marketing authorization;

(b) under section 30 of the Act for the variation of a provision of a product licence, a manufacturer's licence or a wholesale dealer's licence; and

(c) under section 39(4) of the Act for the variation of a provision of a clinical trial certificate,

shall pay the fees mentioned in paragraph (2).

(2) The fees referred to in paragraph (1) are—

(a) the fee prescribed in Part III of Schedule 1 in connection with the application; and

(b) in respect of any inspection of a description referred to in paragraph 1 of Schedule 2 made in connection with the application, the fee payable in accordance with paragraphs 2 to 6 of that Schedule.

Inspections in connection with multiple applications for variations of authorizations and licences

8. Where an inspection is made at a site which has been named as a possible site for manufacture or assembly of a medicinal product, or for the preparation of a substance which is to be used in the manufacture of an immunological product or a blood product, by more than one applicant for a variation to—

(a) a marketing authorization and that site is located outside the United Kingdom; or

(b) a manufacturer's licence and that site is located in the United Kingdom,

the fee in respect of that inspection shall be payable in equal proportions by each of those applicants.

Applications for multiple variations

9.—(1) Subject to paragraph (2), a separate fee shall be payable in respect of each variation of each provision of a marketing authorization, licence or certificate applied for in any one application.

(2) In respect of a variation which is wholly consequential upon another variation of a provision of a marketing authorization, licence or certificate which is applied for in the same application, no separate fee shall be payable.

PART IV

CAPITAL FEES FOR APPLICATIONS FOR RENEWALS OF CLINICAL TRIAL CERTIFICATES AND FOR CERTAIN MANUFACTURER'S LICENCES AND FOR ASSOCIATED INSPECTIONS

Renewals of clinical trial certificates

10. Subject to regulations 19 and 23, in connection with an application under section 38(2) of the Act for renewal of a clinical trial certificate, there shall be payable by the applicant a fee of £2,405.

Renewals of certain manufacturer's licences

11.—(1) Subject to regulation 23, the fee payable in connection with an application for renewal of a manufacturer's licence which is limited solely to the manufacture or assembly of medicinal products the sale or supply of which does not require a marketing authorization or a product licence and to which article 2(2)(i)(e) (exemptions for certain special manufactured products) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(**8**) applies, shall be £85.

(2) In respect of any inspection made in connection with an application referred to in paragraph (1), the fee payable shall be that prescribed in paragraph 2(d) of Schedule 2.

Renewals in terms which are not identical to the existing authorization, licence or certificate

12. Where an applicant applies for renewal of a marketing authorization (other than a Community marketing authorization), a manufacturer's licence, a wholesale dealer's licence or a clinical trial certificate so as to contain provisions which are not identical to the provisions of that authorization, licence or certificate as in force at the date of that application, the fee payable under this Part of these Regulations shall be increased by an amount equal to the fee which would have been payable under Part III of these Regulations had he in addition made a separate application for variation of that authorization, licence or certificate in respect of each provision which is not identical.

PART V

FEES FOR INSPECTIONS MADE DURING THE CURRENCY OF A MARKETING AUTHORIZATION OR LICENCE

Fees for inspections

13.—(1) Subject to paragraph (5) and to regulations 19 and 23, a fee in accordance with paragraphs 2 to 6 of Schedule 2 shall be payable in respect of any inspection of a site made during the currency of a marketing authorization, a manufacturer's licence or a wholesale dealer's licence, except for any inspection in respect of which a fee is otherwise payable under Parts III or IV of these Regulations.

(2) Subject to paragraph (4), the fee payable under paragraph (1) in respect of an inspection of a site made during the currency of a manufacturer's licence or a wholesale dealer's licence shall be payable by the holder of that licence.

(3) Where an inspection is made at a site located outside the United Kingdom and that site is named in more than one marketing authorization as a possible site for the manufacture of the

(**8**) S.I. 1971/1450; to which there are amendments not relevant to these Regulations.

medicinal product in respect of which the authorization is granted the fee payable under paragraph (1) shall be payable in equal proportions by each holder of a marketing authorization in which that site is named as a possible site for manufacture of the medicinal product in respect of which the marketing authorization is granted.

(4) Where an inspection is made at a site located in the United Kingdom and that site is named in more than one manufacturer's licence as a possible site for the manufacture of a medicinal product in respect of which the licence is granted the fee payable under paragraph (1) shall be payable in equal proportions by the holders of those licences.

(5) No fee shall be payable in respect of any inspection of a site carried out within 6 months of a previous inspection in order to ascertain whether alterations or improvements to the premises concerned which were required in writing by the licensing authority as the result of that previous inspection have been carried out.

PART VI

PERIODIC FEES FOR MARKETING AUTHORIZATIONS AND LICENCES

Periodic fees

14.—(1) Subject to paragraphs (2), (4) and (5) and to regulations 19 and 23, there shall be payable by the holder of a marketing authorization (other than a Community marketing authorization), a manufacturer's licence or a wholesale dealer's licence a fee in connection with the holding of the authorization or licence in respect of each fee period during any part of which the authorization or licence is in force.

(2) Marketing authorizations of a type referred to in Part IV of Schedule 3 shall be treated for the purposes of paragraph (1) as if they were one marketing authorization and only one periodic fee in respect of each relevant fee period shall be payable in connection with the holding of such authorizations.

(3) The periodic fee shall be the appropriate fee prescribed in Part III of Schedule 3 and, for the purposes of that Part, Parts I and II of that Schedule shall have effect.

(4) No periodic fee shall be payable in respect of the fee period during which a marketing authorization or licence is first granted except where a marketing authorization was granted pursuant to—

(a) a change of ownership application; or

(b) an application, made no later than three months after the expiry of a marketing authorization, which is for a marketing authorization containing identical provisions to those contained in the expired authorization and which is made by the person who held the expired authorization,

and, in each case, a periodic fee has not been paid in respect of that fee period in connection with the holding of a marketing authorization for the medicinal product to which the authorization relates.

(5) Notwithstanding that an authorization or licence has neither expired nor been revoked, it shall be treated for the purposes of this regulation as not being in force during any part of a fee period if—

(a) not less than three months before the commencement of that fee period, the holder of that authorization or licence has given written notice to the licensing authority indicating that he wishes the authorization or licence to cease to have effect before the commencement of that period; and

(b) no products are sold, supplied or manufactured pursuant to that authorization or licence within that fee period.

PART VII

ADMINISTRATION

Payment of fees to Ministers

15. Any sums which under the provisions of these Regulations become payable by way of, or on account of, fees shall be paid to one of the Ministers specified in section 1(1)(a) (Ministers responsible for the administration of the Act) of the Act.

Time for payment of capital fees in connection with applications or inspections

16.—(1) Subject to paragraph (2) and to regulations 17 and 19, all sums payable by way of capital fees under these Regulations in connection with any application shall be payable at the time of the application.

(2) All sums payable by way of fees in respect of inspections made either in connection with an application for, or during the currency of, an authorization, licence or certificate shall become payable within 14 days following written notice from the licensing authority requiring payment of those fees.

Time for payment of capital fees applications made by small companies

17.—(1) Schedule 4 shall have effect with respect to the capital fee payable in connection with an application made by or on behalf of a small company.

(2) For the purpose of these Regulations, a company is a small company if, for the financial year before that in which the application is made, the amount of its turnover for the financial year is not more than the amount for the time being specified under the heading "*Small company*" in section 247(3) (qualification of company as small or medium-sized) of the Companies Act 1985(**9**); and

(a) its balance sheet total (as defined in section 247(5) of that Act) is not more than the amount for the time being specified under the heading "*Small company*" in section 247(3) of that Act; or

(b) the average number of persons employed by the company in the financial year before that in which the application is made (determined on a weekly basis) does not exceed the number for the time being specified under the heading "*Small company*" in section 247(3) of that Act.

Time for payment of periodic fees

18. All periodic fees shall be payable on the first day of the fee period to which they relate.

Adjustment, waiver, reduction or refund of fees

19.—(1) If after a capital or periodic fee was paid it becomes apparent that—

(a) a lesser fee was properly payable, the excess shall be refunded to the applicant or, as the case may be, the holder of the authorization, licence or certificate concerned: or

(**9**) 1985 c. 6 as amended by section 13(1) of the Companies Act 1989 (c. 40) and by regulation 5(3) of the Companies Act 1985 (Accounts of Small and Medium-Sized Enterprises and Publication of Accounts in ECUs) Regulations 1992 (S.I. 1992/2452). On 1st March 1995 the figures specified in section 247(3) under the heading "*Small company*" applying to the turnover, balance sheet total and number of employees respectively were, £2.8 million, £1.4 million and 50.

(b) a higher fee was properly payable, the balance due shall be payable within l4 days following written notice from the licensing authority to the applicant or, as the case may be, the holder of the authorization, licence or certificate concerned requiring payment of that balance.

(2) The licensing authority shall, to the extent provided in Schedule 5 in relation to capital fees or in Schedule 6 in relation to periodic fees,—

(a) adjust, waive payment of or reduce any fee or part of a fee otherwise payable under these Regulations; or

(b) refund the whole or part of any fee already paid.

Suspension of licences and certificates

20. Where any sum due by way of, or on account of, any fee or any part thereof payable under these Regulations remains unpaid by the holder of a product licence or a product licence of right, a manufacturer's licence, a wholesale dealer's licence or a clinical trial certificate, the licensing authority may serve a written notice on him requiring payment of the sum unpaid and, if after a period of one month from the date of service of such notice, or such longer period as the licensing authority may allow, the said sum remains unpaid, the licensing authority may forthwith suspend the licence or certificate until such sum has been paid.

Civil proceedings to recover unpaid fees

21. All unpaid sums due by way of, or on account of, any fees payable under these Regulations shall be recoverable as debts due to the Crown.

PART VIII

REVOCATION, SAVINGS AND TRANSITIONAL PROVISIONS

Revocation and savings

22.—(1) Subject to paragraph (2), the following regulations (in this regulation called "the revoked Regulations") are hereby revoked—

(a) the Medicines (Products for Human Use Fees) Regulations 1991(**10**);

(b) the Medicines (Products for Human Use Fees) Amendment Regulations 1992(**11**);

(c) the Medicines (Products for Human Use Fees) Amendment Regulations 1994(**12**).

(2) Paragraph (1) shall not affect—

(a) any written notice given or any suspension made under the revoked Regulations and any such notice or suspension shall have effect as if given or made under these Regulations; and

(b) any proceedings constituted under the revoked Regulations for the recovery of any fees due as debts to the Crown.

Transitional provisions

23.—(1) In relation to capital fees, these Regulations shad not apply to any application made before the date on which these Regulations come into force.

(**10**) S.I. 1991/1474; amended by S.I. 1992/756 and S.I. 1994/696.
(**11**) S.I. 1992/756.
(**12**) S.I. 1994/696.

(2) In connection with any periodic fee payable under these Regulations, these Regulations shall not apply—

(a) to any marketing authorization or licence in respect of which the licensing authority has received written notice of surrender prior to the coming into force of these Regulations; or

(b) so as to impose any liability to pay a periodic fee in respect of any period prior to the coming into force of these Regulations.

Signed by authority of the Secretary of State for Health

Tom Sackville
Parliamentary Under Secretary of State,
22nd March 1995 Department of Health

John Redwood
23rd March 1995 Secretary of State for Wales

Fraser of Carmyllie
24th March 1995 Minister of State, The Scottish Office

Angela Browning
Parliamentary Secretary, Ministry of Agriculture,
11th April 1995 Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on

L.S.

F. A. Elliott
13th April 1995. Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on

L.S.

J. Murray
19th April 1995. Permanent Secretary

We consent,

Tim Kirkhope
Andrew Mitchell
Two of the Lords Commissioners of Her Majesty's Treasury

20th April 1995

SCHEDULE 1 Regulations 2(1), 4(a) and 7(2)(a)

CAPITAL FEES FOR APPLICATIONS FOR, AND VARIATIONS TO, MARKETING AUTHORIZATIONS, LICENCES AND CERTIFICATES

PART I

INTERPRETATION

1. In this Schedule—

"active ingredient" means an ingredient of a medicinal product in respect of which efficacy is claimed (whether therapeutic, diagnostic or otherwise);

"complex application" means an application, other than a major application, for a marketing authorization where the application falls within one or more of the descriptions specified in sub-paragraphs (a) to (n)—

(a) the application relates to a medicinal product which is intended to be used in accordance with an indication for use in respect of a new category of patients or as treatment for a new category of disease;

(b) the application relates to a medicinal product containing a new combination of active ingredients that have not previously been included in that combination in a medicinal product in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(c) the application relates to a medicinal product containing a new excipient;

(d) the application relates to a medicinal product that is intended to be administered by a route of administration different from that used in the administration of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(e) the application relates to a medicinal product containing an active ingredient the manufacture of which involves a route of synthesis (or, in the case of a medicinal product not synthetically produced, a method of manufacture) different from that used in the manufacture of the active ingredient of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(f) the application relates to a medicinal product which is a controlled release preparation and is not a simple application;

(g) the application relates to a sterile medicinal product the manufacture of which involves a method of sterilisation different from that used in the manufacture of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(h) the application relates to a sterile medicinal product the container of which is directly in contact with the medicinal product and is made from different material from the container of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(i) the application names as manufacturer of the active ingredient of the medicinal product in question a different manufacturer from the manufacturer of that active ingredient

included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(j) the application relates to a medicinal product which is an influenza vaccine and in respect of which the manufacturer or the manufacturing process is different from that specified in any other marketing authorization which the applicant holds in respect of that product;

(k) the application is for the grant of a marketing authorization for a medicinal product which is an influenza vaccine, except where it relates only to an influenza vaccine containing a different strain or strains from that specified in any other marketing authorization which the applicant holds;

(l) the application is for the grant of a marketing authorization for a medicinal product which is to be delivered by way of a metered dose inhaler;

(m) the application is for the grant of a marketing authorization for a medicinal product which is in a powdered form and is to be delivered by way of inhalation;

(n) the application relates to a medicinal product

(i) which is administered to the site of action or absorption by a method which has not previously been authorised in relation to any authorised medicinal product which contains the same active ingredient as the product in question and,

(ii) in respect of that other product, a marketing authorization (other than a product licence of right) has previously been granted;

"decentralised incoming application" means a major application, a complex application or a standard application for a marketing authorization for a medicinal product in respect of which—

(a) a marketing authorization has already been granted in another member State; and

(b) recognition of that marketing authorization is sought from the licensing authority by way of the grant of a marketing authorization in the United Kingdom, pursuant to the procedure in Chapter III of Directive 75/319/EEC(**13**);

"major application" means an application relating to a medicinal product containing a new active ingredient;

"new active ingredient" means an active ingredient that 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 previously been granted;

"new excipient" means any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product—

(a) which is intended to be administered by the same route of administration as the product in question; and

(b) in respect of which a marketing authorization (other than a product licence of right) has previously been granted, except that in the case of a medicinal product intended to be administered orally, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Community as an approved ingredient or additive in food or in a food product;

"simple application" means—

(**13**) OJ No. L147, 9.6.75. p. 13. Chapter III was replaced by Article 3 (1) of Directive 93/39/EEC (OJ No. L214, 24.8.93, p. 22).

(a) an application for a marketing authorization to which Article 4.8(a)(i) of Council Directive 65/65/EEC(**14**) applies other than one for a marketing authorization for a medicinal product which is a new strength of a product in respect of which a marketing authorization has previously been granted in the United Kingdom: or

(b) an application, made no later than three months after the expiry of a marketing authorization, which is for a marketing authorization containing identical provisions to those contained in the expired authorization and which is made by the person who held the expired authorization;

"standard application" means any application for the grant of a marketing authorization which is not a major application, a complex application, a simple application, a change of ownership application or an application for a marketing authorization (parallel import).

PART II

CAPITAL FEES FOR APPLICATIONS FOR AUTHORIZATIONS, LICENCES AND CERTIFICATES

Marketing authorizations

1.—(1) Subject to paragraphs 2, 3 and 4, the fee payable under regulation 4(a) in connection with an application for a marketing authorization 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—

TABLE

Column 1 Kind of application	Column 2 Fee payable
1. Major application	(a) (a) £20,165
(a) in respect of any such application to which Section G of Part 4 of the Annex to Council Directive 75/318/EEC(**15**) applies	
(b) (b) which is a decentralised incoming application	(b) (b) £50,365
(c) (c) in any other case	(c) (c) £71,950
2. Complex application	(a) (a) £10,305
(a) which is a decentralised incoming application	
(b) (b) in any other case	(b) (b) £14,725
3. Standard application	(a) (a) £4,255
(a) which is a decentralised incoming application	

(**14**) OJ No. 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).

(**15**) OJ No. L147, 9.6.75, p. 1. The Annex was replaced by the Annex to Council Directive 91/507/EEC (OJ No. L270, 26.9.91, p. 32).

Column 1 Kind of application	Column 2 Fee payable
(b) (b) in any other case	(b) (b) £6,080
4. Simple application	**4.** £1,710
5. Application for a marketing authorization (parallel import)	**5.** £1,700
6. Change of ownership application	**6.** £790

(2) Each reference in paragraphs 3 and 4 to an amount payable under paragraph 1 in respect of an application refers to the amount payable under that paragraph in respect of an application of the kind in question.

2. Where a major application is made by a person who is already the holder of a clinical trial certificate in respect of a medicinal product containing the same active ingredient as the medicinal product in respect of which the marketing authorization is applied for, the fee payable under regulation 4(a) in connection with that application shall be reduced by the amount of the fee paid in connection with the application for that certificate.

3.—(1) In this paragraph—

"joint development" means the development by two or more applicants for marketing authorizations relating to medicinal products—

(a) each of which contains the same new active ingredient or combination of new active ingredients but with different proprietary names and which does not require separate consideration by a committee established under section 4 (establishment of committees) of the Act or by the Medicines Commission; and

(b) the development of which has been notified to the licensing authority at or before the time the application is submitted, as being a joint development undertaken by those applicants; and

(c) in respect of which applications for marketing authorizations have been received by the licensing authority within one month of each other;

"primary applicant" means —

(a) that party to a joint development who first makes an application for a marketing authorization relating to a new active ingredient which was the subject of that joint development; or

(b) that party to a joint development who first makes an application for a marketing authorization relating to a different dosage form or strength of that new active ingredient;

"secondary applicant" means any party to a joint development, other than the primary applicant, who makes an application for a marketing authorization relating to the same new active ingredient as that which was the subject of the application made by the primary applicant.

(2) Subject to sub-paragraph (3), where a joint development relates to a medicinal product and two or more applications for marketing authorizations are submitted to the licensing authority by parties to the joint development, the fee payable under regulation 4(a) shall be the amount payable in respect of a major application under paragraph 1 plus—

(a) in respect of the first or only marketing authorization applied for by that secondary applicant, the amount payable in respect of a complex application under paragraph 1;

(b) in respect of each additional marketing authorization applied for by that secondary applicant which relates to a medicinal product of the same dosage form, the amount payable in respect of a standard application under paragraph 1;

(c) in respect of the first additional marketing authorization applied for by that secondary applicant relating to that medicinal product which is of a different dosage form, the amount payable in respect of a complex application under paragraph 1 and in respect of any other such application by that secondary applicant, the amount payable in respect of a standard application under paragraph 1.

(3) Where a joint development relates to a medicinal product and an application for an additional marketing authorization is submitted by both the primary applicant and the secondary applicant, both or all of which applications relate to identical dosage forms and strengths of that product—

(a) where the amount payable by the primary applicant is that in respect of a complex application, the fee payable under regulation 4(a) by the secondary applicant shall be that in respect of a standard application under paragraph 1;

(b) where the amount payable by the primary applicant is that in respect of a standard application, the fee payable under regulation 4(a) by the secondary applicant shall be that in respect of a simple application under paragraph 1.

4.—(1) Subject to sub-paragraphs (2) and (3), where an application for a marketing authorization is for more than one such authorization each relating to a medicinal product containing the same active ingredient or combination of ingredients, the fee payable under regulation 4(a) shall be of an amount equal to the aggregate of the amounts payable under paragraph 1 in respect of a separate application for each such authorization.

(2) If the application is a major application, the amount payable shall be the amount payable in respect of a major application under paragraph 1 plus—

(a) in respect of each additional marketing authorization applied for which relates to a medicinal product of a different dosage form with a different route of administration, the amount payable in respect of a complex application under paragraph 1;

(b) in respect of each additional marketing authorization applied for which relates to a medicinal product of a different dosage form but with the same route of administration, the amount payable in respect of a standard application under paragraph 1; and

(c) in respect of each additional marketing authorization applied for which relates to a medicinal product of the same dosage form but of a different strength of active ingredient or different combination of active ingredients, the amount payable in respect of a standard application under paragraph 1.

(3) If the application is a complex application, the amount payable shall be the amount payable in respect of a complex application under paragraph 1 plus—

(a) in respect of each additional marketing authorization applied for which relates to a medicinal product of a different dosage form with a different route of administration, the amount payable in respect of a complex application under paragraph 1;

(b) in respect of each additional marketing authorization applied for which relates to a medicinal product of a different dosage form but with the same route of administration, the amount payable in respect of a standard application under paragraph 1; and

(c) in respect of each additional marketing authorization applied for which relates to a medicinal product of the same dosage form but of a different strength of active ingredient or different combination of active ingredients, the amount payable in respect of a standard application under paragraph 1.

Manufacturer's licences

5.—(1) The fee payable under regulation 4(a) in connection with an application for a manufacturer's licence shall be—

(a) in a case to which sub-paragraph (2) applies, £95;

(b) in any other case, £1,690.

(2) This sub-paragraph applies to the case of an application for a manufacturer's licence which is limited solely to the manufacture or assembly of medicinal products which are to be sold or supplied in circumstances to which article 2 (2)(i)(e) (exemptions for certain special manufactured products) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(**16**) applies.

Wholesale dealer's licences

6.—(1) Subject to sub-paragraph (2), the fee payable under regulation 4(a) in connection with an application for a wholesale dealer's licence shall be £780.

(2) The fee payable under regulation 4(a) shall be £475 where an application for a 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 but where the total turnover of the sale by way of wholesale dealing of authorised medicinal products does not exceed £30,000; or

(c) relates only to medicinal products falling within a description or class specified in an Order which is for the time being in force made under section 51(1) (general sale lists) of the Act.

(3) For the purposes of sub-paragraph (2)(a) and (b), turnover shall be calculated in accordance with the provisions of Part II of Schedule 3.

Clinical trial certificates

7. The fee payable under regulation 4(a) in connection with an application for a clinical trial certificate shall be £14,465.

PART III

CAPITAL FEES FOR APPLICATIONS FOR VARIATIONS OF AUTHORIZATIONS, LICENCES AND CERTIFICATES

Marketing authorizations

1. In this Part of this Schedule—

"Type I Application" means an application by a marketing authorisation holder to vary a marketing authorization (not being a marketing authorization (parallel import)) which is a "minor variation" within the meaning of Article 3.1(a) of Regulation (EC) No. 541/95(**17**);

(**16**) S.I. 1971/1450.
(**17**) OJ No. L55, 11.3.95,p. 7.

"Type II Application" means any application to vary a marketing authorization (not being a marketing authorization (parallel import) or a product licence of right) which is neither a Type I Application nor an application for a Type II complex variation nor a change to which Annex II to Commission Regulation (EC) 541/95 applies;

"Type II complex variation" means a variation of a marketing authorization which relates to a change—

(a) in the formulation of a medicinal product comprising one or more of the following

(i) a change which necessitates in-vivo bioavailability studies to be performed on that product:

(ii) a change in that product's preservative system; or

(iii) a change in that product's excipients which significantly affects the pharmaceutical or the therapeutic properties of that product; or

(b) in the therapeutic indications of a medicinal product, such as a change in respect of use in a new category of patients or as a treatment for a new category of disease, other than a change to which paragraph 2 (changes to therapeutic indications) of Annex II to Commission Regulation (EC) No. 541/95 applies;

(c) in the composition, manufacture or use of a medicinal product to which any one or more of paragraphs (c), (e), (g) to (j) or (n) of the definition of complex application would apply where an application for a marketing authorisation is made in respect of a medicinal product.

2. Subject to paragraphs 3 to 6 and 13 and 14, the fee payable under regulation 7(1) in connection with an application for variation of a marketing authorization shall be—

(a) where the application is a Type I Application, £190;

(b) where the application is a Type II Application, £342;

(c) where the application is for a Type II complex variation, £8,766.

3. Where, for the purposes of Commission Regulation (EC) No. 541/95, the United Kingdom is the reference member State as defined in Article 2.2 of that Regulation, the fee payable under regulation 7(1) in connection with an application for variation of a marketing authorization shall be—

(a) where the application is a Type I Application, £230;

(b) where the application is a Type II Application, £410;

(c) where the application is for a Type II complex variation, £10,520.

4. Subject to paragraph 5, where a marketing authorization has been granted in accordance with an application to which Section G of Part 4 of the Annex to Council Directive 75/318/EEC(**18**) applies, the fee in connection with the first application for variation of that marketing authorization made within 5 years of the date of the grant of that marketing authorization, so as to authorise use of the medicinal product in a new therapeutic area, shall, in addition to the fee payable under regulation 7(1), be the difference between the fee paid in connection with that application and the fee which would have been payable had the application been a major application.

5. Paragraph 4 shall not apply where the first application for variation of the marketing authorization relates to a therapeutic area, in respect of which the applicant would be entitled (had he not already held a marketing authorization) to apply for a marketing authorization to which Section G of Part 4 of the Annex to Council Directive 75/318/EEC applies.

(**18**) OJ No. L147, 9.6.75, p. 1. The Directive was amended by Directives 89/341/EEC (OJ No. L142, 25.5.89, p. 11), 91/507/EEC (OJ No. L270, 26.9.91, p. 32) and 93/39/EEC (OJ No. L214, 24.8.93, p. 22).

6. The fee payable under regulation 7(1) in connection with an application for variation of a marketing authorization (parallel import)—

(a) where the variation applied for falls within one of the following sub-paragraphs

(i) a change of either or both of the name and the address of the holder of the authorization;

(ii) a change of either or both of the name and the address of a manufacturer, assembler, storer or distributor named in the authorization where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise, and any change of address does not involve a change of the site of manufacture, assembly or storage or of the site from which distribution takes place;

(iii) the removal from the authorization of details of one or more of the sites of manufacture, assembly or storage or of the sites from which distribution takes place;

(iv) the removal from the authorization of details of any of the activities to which the authorization relates;

(v) the removal from the authorization of details of any of the medicinal products which the holder of the authorization is authorized to import;

shall be £95; and

(b) in any other case, shall be £310.

Manufacturer's licences

7. Subject to paragraphs 8 and 13, the fee payable under regulation 7(1)(b) in connection with an application for variation of a manufacturer's licence shall be—

(a) in the case of a manufacturer's licence referred to in paragraph 5(2) of Part II of this Schedule, £90; and

(b) in any other case, £180.

8. The fee payable under regulation 7(1)(b) in connection with an application for variation of a manufacturer's licence shall be £90 in respect of each variation applied for which constitutes a change to the licence not requiring an inspection or medical, scientific or pharmaceutical assessment.

Wholesale dealer's licences

9. Subject to paragraphs 10 and 13, the fee payable under regulation 7(1)(b) in connection with an application for a variation of a wholesale dealer's licence shall be £210.

10. The fee payable under regulation 7(1)(b) in connection with an application for variation of a wholesale dealer's licence shall be £90 in respect of each variation applied for which consists of a change to the licence not requiring an inspection or medical, scientific or pharmaceutical assessment.

Clinical trial certificates

11. Subject to paragraphs 12 and 13, the fee payable under regulation 7(1)(c) in connection with an application for variation of a clinical trial certificate shall be £240.

12. Where an application is made for a variation to a provision of a clinical trial certificate and the variation applied for consists of no more than a change of either or both the name and address of the holder of the certificate, the fee payable under regulation 7(1)(c) shall be £90.

Identical variations

13. Subject to paragraph 14, where more than one application by the same applicant is made at the same time for the variation of a marketing authorization, a manufacturer's licence, a wholesale dealer's licence or a clinical trial certificate and where the applications are for identical variations, the fee payable under regulation 7(1)—

(a) in connection with the first application considered by the licensing authority shall be the appropriate amount specified in this Part of this Schedule:

(b) in connection with each of the other applications shall be 50% of that amount.

14. Where more than one application for a Type II complex variation is made at the same time by the same applicant for the variation of a marketing authorization, the fee payable under regulation 7(1)

(a) in connection with the first application considered by the licensing authority shall be the appropriate amount specified in this Part of the Schedule;

(b) in connection with each of the other applications where the applications are for identical variations and in respect of which no further medical, scientific or pharmaceutical assessment is required shall be the amount which would be payable if the application was a Type II Application.

SCHEDULE 2 Regulations 4(b), 7(2)(b), 11(2) and 13(1)

FEES FOR INSPECTIONS

Interpretation

1.—(1) In this Schedule—

"major inspection" means an inspection at a site at which 60 or more, but fewer than 250, relevant persons are employed;

"minor inspection" means an inspection at a site at which fewer than 10 relevant persons are employed;

"relevant person" means any person directly or indirectly engaged in, or assisting in, the manufacture or assembly of medicinal products and includes any person connected with such production who is involved in management, quality control, site maintenance, packing, storage or distribution;

"standard inspection" means an inspection at a site at which 10 or more, but fewer than 60, relevant persons are employed;

"supersite inspection" means an inspection at a site at which 250 or more relevant persons are employed.

(2) In calculating the number of relevant persons for the purposes of this Schedule, any person partly engaged in or assisting in the manufacture or assembly of medicinal products (whether as a part-time employee or by virtue of being only partly employed in such work) shall be included in the calculation but only as a fraction calculated by reference to the amount of time spent by that person engaged or assisting in the manufacture or assembly of medicinal products or, where such a calculation is inappropriate, by reference to the percentage of his job which relates to the manufacture or assembly of such products and, in either case, by comparison with the average working week of a relevant person engaged in full-time employment at the same site.

(3) Any reference in sub-paragraphs (1) and (2) to the manufacture or assembly of medicinal products includes a reference to the preparation of substances which are used in the manufacture of an immunological product or a blood product.

Fees

2. Subject to paragraphs 3 to 6, the fee payable in respect of an inspection under these Regulations shall be—

(a) except in the case of an inspection falling within sub-paragraphs (b) to (d)—

(i) in respect of a minor inspection, £1,560;

(ii) in respect of a standard inspection, £2,945;

(iii) in respect of a major inspection, £4,750:

(iv) in respect of a supersite inspection, £9,025;

(b) where the site inspected is wholly or partly concerned with the manufacture of sterile products or the filling of the containers directly in contact with such products—

(i) in respect of a minor inspection, £1,740;

(ii) in respect of a standard inspection, £4,890;

(iii) in respect of a major inspection, £7,885;

(iv) in respect of a supersite inspection, £15,010;

(c) except in the case of an inspection falling within sub-paragraph (b) or (d), where the site inspected is concerned only with the assembly of medicinal products

(i) in respect of a minor inspection, £600;

(ii) in respect of a standard inspection, £1,680;

(iii) in respect of a major inspection, £2,790;

(iv) in respect of a supersite inspection, £5,225;

(d) where the site inspected is limited solely to the manufacture or assembly of medicinal products, the sale or supply of which does not require a marketing authorization and to which article 2(2)(i)(e) (exemption for certain special manufactured products) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 applies, £115.

3.—(1) Where any inspection at a site would be a supersite inspection and that site consists of two or more separate manufacturing operations on different parts of the site, an inspection may, pursuant to a request in writing from the applicant or, as the case may be, the marketing authorization or licence holder, relate to one or more manufacturing operations at that site.

(2) An inspection referred to in sub-paragraph (1) shall be categorised in accordance with the number of relevant persons employed in each manufacturing operation which is inspected as if that operation constituted the entire site, and the fee payable for that inspection shall be the appropriate fee specified for that category in paragraph 2, or if more than one manufacturing operation is inspected, the aggregate of the appropriate fees shall be payable.

4.—(1) Subject to sub-paragraph (2), unless the applicant or, as the case may be, the holder of the marketing authorization or licence establishes that an inspection is a minor inspection, standard inspection or major inspection, the fee payable shall be the appropriate fee specified in paragraph 2 for a supersite inspection.

(2) If, following an inspection, it becomes apparent that the inspection fell into a different category from that established by the applicant or the holder of the marketing authorization or

licence, the fee payable in respect of that inspection shall be the fee payable in respect of an inspection falling within the category into which the inspection should have fallen.

5.—(1) In the case of an inspection of a site in connection with the grant, variation or renewal of a wholesale dealer's licence or during the currency of such a licence, the fee payable shall be £315 in a case falling within sub-paragraph (2) and, in any other case, £690.

(2) The cases referred to in paragraph (1) are cases where—

(a) the site is that of a wholesale dealer whose licence is limited to dealing only in medicinal products falling within a description or class specified in an Order made under section 51(1) (general sale lists) of the Act;

(b) the site relates to a registered pharmacy as referred to in paragraph 6(2) of Part II of Schedule 1; or

(c) the total turnover in respect of sales by way of wholesale dealing in authorised medicinal products of the wholesale dealer does not exceed £30.000.

6. The fee payable in respect of an inspection at a site outside the United Kingdom shall be increased by an amount equal to the travelling and subsistence costs of the inspector relating to the inspection and any additional costs (such as interpreters' fees) reasonably incurred by him in respect of that inspection as a result of its being at a site outside the United Kingdom.

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	

Column 1 Kind of product	Column 2 Fee payable
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(**19**), 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

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

(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.

(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(**20**) 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.

SCHEDULE 4

Regulation 17 (1)

TIME FOR PAYMENT OF CAPITAL FEES — APPLICATIONS MADE BY SMALL COMPANIES

1. In this Schedule a reference to an application is to an application made by or on behalf of a small company.

2. In connection with a major application for a marketing authorization for which the fee payable is that specified in entry 1(c) of the Table in paragraph 1 of Part II of Schedule 1, the fee payable under regulation 4(a) shall, if the applicant so requests in writing, be payable as to 25% at the time of

(**20**) OJ No. 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).

the application and as to 75% within 30 days following written notice from the licensing authority that the application has been determined.

3. In connection with a complex application for a marketing authorization, the fee payable under regulation 4(a) shall, if the applicant so requests in writing, be payable as to 50% at the time of the application and as to 50% within 30 days following written notice from the licensing authority that the application has been determined.

4. In connection with an application to which paragraph 4 of Part II of Schedule 1 applies, the fee payable under regulation 4(a) shall, if the applicant so requests in writing, be payable—

(a) as to 50% of the aggregate payable in accordance with that paragraph at the time of the application; and

(b) as to 50% of that aggregate within 30 days following written notice from the licensing authority that the application has been determined.

5. In connection with an application for a manufacturer's licence or a wholesale dealer's licence, the fee payable under regulation 4(a) shall, if the applicant so requests in writing, be payable as to 50% at the time of the application and as to 50% 12 months after that time.

6. In connection with an application for a marketing authorization, manufacturer's licence or wholesale dealer's licence, the fee payable in respect of an inspection at any site other than one named as a possible site for manufacture of a medicinal product by three or more applicants shall, if the applicant so requests in writing, be payable as to 50% within the period of 14 days referred to in regulation 16(2) and as to 50% 12 months after that date.

SCHEDULE 5

Regulation 19(2)

WAIVER, REDUCTION OR REFUND OF CAPITAL FEES

1. Where the manufacture, assembly, sale or supply of medicinal products of a particular class or description will be, or is likely to be, interrupted for a period and in consequence thereof the health of the community will be, or is likely to be, put at risk, any capital fees payable under these Regulations in connection with an application for the grant of a marketing authorization or a manufacturer's licence relating to a medicinal product falling within that class or description and made during that period or, if the period will, or is likely to, exceed 3 months, during the first 3 months of that period, shall be waived.

2. Where, at the specific written request of the licensing authority, an application is made for the variation of a marketing authorization so as to—

(a) restrict any one or more of the indications, dosage or target population, or

(b) add a contraindication or a warning or both of these,

as a consequence of new information having a bearing on the safe use of the product, the fee payable under regulation 7(1) shall be refunded or, if it has not yet been paid, shall be waived.

3.—(1) Subject to sub-paragraphs (2) and (3), where an application for the grant of, or for a variation to, a marketing authorization or a clinical trial certificate, or for the renewal of a clinical trial certificate is withdrawn before determination by the licensing authority, the following percentage of the fee otherwise payable under regulations 4(a), 7(1) or 10 in connection with that application shall be refunded or, if it has not yet been paid, shall be waived—

(a) if the application has been received but no medical, scientific or pharmaceutical assessment thereof has begun, 90%;

(b) except in a case to which sub-paragraph (c) applies. if medical, scientific or pharmaceutical assessment has begun but not been completed, 50%;

(c) if a request for further information in connection with the application has been made by the licensing authority under section 44(1) (provision of information to licensing authority) of the Act, 25%.

(2) In a case to which sub-paragraph (1)(a) applies, that provision shall not have effect so as to render an applicant liable to pay more than £1,500 in respect of the fee in connection with that application.

(3) If an application for the grant of, or for a variation to, a marketing authorization or clinical trial certificate, or for the renewal of a clinical trial certificate, is withdrawn either after medical, scientific and pharmaceutical assessment has been completed or following consideration of that application by a committee established under section 4 (establishment of committees) of the Act or by the Medicines Commission, no refund or waiver of the fee payable under regulation 4(a), 7(1) or 10 in connection with that application shall be made under this paragraph.

4. Where an application for the grant of, or for a variation to, a manufacturer's or a wholesale dealer's licence is withdrawn before determination by the licensing authority, the following percentage of the fee otherwise payable under regulation 4(a) or 7(1) in connection with that application shall be refunded or, if it has not yet been paid, shall be waived—

(a) if the application is withdrawn before any inspection in connection with that application has been made, 90%;

(b) if such an inspection has been made, 50%.

5. Where the same site is inspected at the same time in connection with applications for the grant or variation of both a manufacturer's licence and a wholesale dealer's licence or during the currency of both such licences, the fee otherwise payable under these Regulations in respect of the inspection relating to the wholesale dealer's licence shall be waived.

6. In relation to a marketing authorization (parallel import), the fee payable in respect of each such application shall be waived—

(a) where the authorization relates to a medicinal product in respect of which a separate marketing authorization has been granted pursuant to the provisions of Council Directive 65/65/EEC in more than one member State, those marketing authorizations are indicated on the marketing authorization (parallel import) as having been validly granted in those member States and the holder of that authorization applies for the grant of a separate marketing authorization (parallel import) in respect of each marketing authorization which has been granted and so indicated; or

(b) the holder of the authorization applies for a variation to the authorization solely relating to a change in the number of a marketing authorization referred to in sub-paragraph (a).

(3) Where a marketing authorization is varied so as to include the provisions of another marketing authorization in the circumstances set out in paragraph 4(4) of Part III of Schedule 3, the fee payable in respect of that variation under regulation 7(1) shall be refunded or, if it has not yet been paid, shall be waived.

SCHEDULE 6

Regulation 19(2)

ADJUSTMENT, REDUCTION OR REFUND OF PERIODIC FEES

1. Where, after payment of any periodic fee payable in accordance with the provisions of these Regulations, the marketing authorization in respect of which such a fee has been paid is either

surrendered at the specific written invitation of the licensing authority, or is revoked by the licensing authority on a date earlier than the date of expiry stated in the marketing authorization, the licensing authority shall refund to the applicant the whole or any part of the difference between such periodic fee as has been paid and the amount of the periodic fee payable on the basis of the actual duration of the marketing authorization or licence up to the date of such surrender or revocation.

2. Any sums payable to the applicant by way of refund of any fees under the provisions of this Schedule may be treated as having been paid on account of any other fee which the applicant is liable to pay (whether by instalments or otherwise) under the provisions of these Regulations.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision for the fees payable under the Medicines Act 1971 in respect of marketing authorizations, licences and certificates relating to medicinal products for human use.

Parts II, III and V and Schedules 1 and 2 provide for capital fees to be payable in connection with applications for, or variations to, marketing authorizations, manufacturer's licences, wholesale dealer's licences, clinical trial certificates and certificates permitting the export of medicinal products and for associated inspections. Most of these fees were previously provided for by the regulations revoked by these Regulations but there are two exceptions—

(a) a new category of fee is introduced in respect of decentralised incoming applications which are applications for marketing authorizations, in respect of which recognition is sought of any authorization already granted by another member State of the European Community;

(b) Part III of Schedule I imposes a new scheme for the classification of fees for variations to marketing authorizations, based on that set out in Commission Regulation (EC) No. 541/95 (OJ No. L55, 11.3.95, p. 7).

In general the fees prescribed by these Regulations are the same or lower than those which they replace. Two exceptions occur in relation to applications for the variation of marketing authorizations. Here fees of £190 and £342 replace fees of £100 and £235 which have applied to applications for the variation of product licences. However, owing to a revision of the categories of variation many applications which previously would have attracted a fee of £325 will, under these Regulations, attract a fee of £190. Overall it is estimated that the new fee levels will result in a reduction of the yield from fees of about 4%.

Part VI of, and Schedule 3 to, the Regulations impose periodic fees to be payable in connection with the holding of marketing authorizations, manufacturer's licences and wholesale dealer's licences. The amount of the periodic fee varies according to the type of product and, in some cases, according to turnover. Excepted from the requirement to pay periodic fees are holders of clinical trial certificates and certain manufacturer's licences who are required to pay fees on renewal of their certificates or licences (Part IV).

Regulation 23 contains transitional provisions.

Administrative provisions (Part VII, Schedules 4, 5 and 6) deal with time of payment and waiver or refund of both capital and periodic fees in specified circumstances. Special arrangements are provided in respect of the time of payment of capital fees by small companies and a new

concession is introduced in respect of small companies who make complex applications for marketing authorizations (Schedule 4).

Part VIII of the Regulations revokes the earlier Regulations relating to fees for medicinal products for human use and also makes saving and transitional provisions.

An assessment of the cost to business of complying with these Regulations has been made, copies of which have been placed in the libraries of both Houses of Parliament and further copies of which may be obtained from the Medicines Control Agency, Department of Health, Room 1207, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.