STATUTORY INSTRUMENTS

1991 No. 1474

MEDICINES

The Medicines (Products for Human Use — Fees) Regulations 1991

Made - - - -	*27th June 1991*
Laid before Parliament	*27th June 1991*
Coming into force - -	*18th July 1991*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and in Scotland, 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:

PART I

GENERAL

Citation, commencement and scope

1.—(1) These Regulations may be cited as the Medicines (Products for Human Use — Fees) Regulations 1991, and shall come into force on 18th July 1991.

(**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.

(**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.

(2) Subject to paragraph (3) below, these Regulations apply only to fees payable—

(a) in connection with applications for the grant, variation or renewal of licences or certificates under Part II of the Medicines Act 1968(**4**) relating wholly or partly to medicinal products for human use;

(b) in respect of inspections made in connection with applications for the grant, variation or renewal of, or during the currency of any such licence;

(c) in connection with the holding of such licences.

(3) No fee shall be payable under these Regulations in connection with any application for the grant, variation or renewal of a licence or certificate under Part II of the Act where that application is made at the specific written invitation of the licensing authority.

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 that Act;

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

"licence fee period" means the period beginning with the coming into force of these Regulations and ending on 31st March 1992 and subsequently, the period beginning with the first day of April in any year and ending with the last day of March in the following year;

"medicinal product" includes any substance or article specified in any order made under section 104 or 105(1)(a) 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 (parallel import)" means a product licence in respect of a medicinal product which is imported into the United Kingdom from another Member State of the European Economic Community, in respect of which there has been granted a marketing authorisation in another Member State of that Community and which has no differences having therapeutic effect from a medicinal product in respect of which a product licence has previously been granted in the United Kingdom;

"relevant licence fee period" means any licence fee period during any part of which a licence in respect of which a periodic fee is payable is in force.

(2) The interpretation provisions contained in Part I of Schedule 1 and Parts I and II of Schedule 3 shall have effect.

(3) 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, and any reference in a regulation, Schedule or Part of a Schedule, to a numbered paragraph shall be construed as a reference to a paragraph of that regulation or, as the case may be, Schedule, or Part of a Schedule bearing that number.

Fees payable in connection with applications and inspections

3.—(1) Subject to paragraph (2), 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.

(**4**) 1968 c. 67.

(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.

PART II

CAPITAL FEES FOR APPLICATIONS FOR LICENCES OR CERTIFICATES AND FOR ASSOCIATED INSPECTIONS

Applications for licences and certificates

4. Subject to regulations 5, 19 and 23, in connection with an application for a product licence, 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 of a description falling within paragraph 1 of Schedule 2 made in connection with that application the fee payable in accordance with paragraphs 2 to 5 of that Schedule.

Inspections in connection with multiple applications for 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 by more than one applicant for—

(a) a product licence 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 applicant in connection with an application for such licence.

Applications for certificates by exporters of medicinal products

6.—(1) In connection with an application for a certificate issued under section 50 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 £150;

(b) in any other case, a fee of £75; and

(c) in either case—

(i) a fee of £75 for each set of certificates requested by the applicant in addition to one; and

(ii) a fee of £15 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)(i) above, "set of certificates" means an original certificate plus up to four certified copies of that certificate.

PART III

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

Variations of licences and certificates

7. Subject to regulations 8, 9, 19 and 23, in connection with an application 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 under section 39(4) for the variation of a clinical trial certificate, there shall be payable by the applicant—

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

(b) in respect of any inspection of a description referred to in paragraph 1 of Schedule 2 made in connection with that application, the fee payable in accordance with paragraphs 2 to 5 of that Schedule.

Inspections in connection with multiple applications for variations of licences

8. Where an inspection mentioned in regulation 7(b) is made at a site which has been named as a possible site for manufacture or assembly of a medicinal product by more than one applicant for a variation to—

(a) a product licence 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 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 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 MANUFACTURERS' LICENCES AND FOR ASSOCIATED INSPECTIONS

Renewals of clinical trial certificates

10. Subject to regulations 12, 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 £3,500.

Renewals of certain manufacturers' licences

11.—(1) Subject to regulations 12 and 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 do not require a product licence and to which

Article 2(2)(i)(e) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(**5**) applies shall be £80.

(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 certificate or licence

12. Where an applicant applies for the renewal of a certificate or licence so as to contain provisions which are not identical to that certificate or licence as in force at the date of that application, he shall pay, in addition to any fee otherwise payable in respect of that renewal under this Part of these Regulations, a fee equal to the fee which would have been payable under Part III of these Regulations had he made a separate application for each variation of that certificate or licence.

PART V

FEES FOR INSPECTIONS MADE DURING THE CURRENCY OF A LICENCE

Fees payable

13.—(1) Subject to paragraph (5) and to regulations 19 and 23, a fee in accordance with paragraphs 2 to 5 of Schedule 2 shall be payable in respect of any inspection of a site made during the currency of a product licence, 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 a fee is payable under paragraph (1) in respect of an inspection of a site located outside the United Kingdom, the fee shall be payable in equal proportions by each holder of a product licence in which that site is named as a possible site for manufacture of the medicinal product in respect of which the product licence is granted.

(4) In a case where a site located in the United Kingdom is named as a possible site for the manufacture of a medicinal product and in respect of which two or more manufacturers' licences are in force, any 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 LICENCES

Fees payable

14.—(1) Subject to paragraphs (2) and (4) and to regulations 19 and 23, there shall be payable by the holder of a product licence (including a product licence of right), a manufacturer's licence or

(**5**) S.I. 1971/1450; there are no relevant amending instruments.

a wholesale dealer's licence a fee in connection with the holding of the licence in respect of each licence fee period during any part of which the licence is in force.

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

(3) The periodic fee shall be the appropriate fee prescribed in Part III of Schedule 3.

(4) No periodic fee shall be payable in respect of the licence fee period during which a licence is first granted.

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) 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, a 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 in section 248(1)(a) of the Companies Act 1985(**6**); and

(a) its balance sheet total (as defined in section 248(3) of that Act) is not more than the amount for the time being specified in section 248(1)(b) 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 in section 248(1)(c) of that Act.

Time for payment of periodic fees

18.—(1) Subject to paragraph (2), all periodic fees shall be payable on the first day of the licence fee period to which they relate.

(**6**) 1985 c. 6, as amended by section 13(3) of the Companies Act 1989 (c. 40). The figures currently specified in section 248(1)(a), (b) and (c) are, respectively, £2 million, £975,000 and 50.

(2) Periodic fees payable in respect of the licence fee period beginning with the date of coming into force of these Regulations, shall be payable within 28 days of receipt of a written notice given by the licensing authority requiring payment of such fees.

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 licence or certificate concerned; or

(b) a higher fee was properly payable, the balance due shall be payable within 14 days following written notice from the licensing authority to the applicant or, as the case may be, the holder of the 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 or 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 licence or certificate, the licensing authority may serve a 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, that sum remains unpaid, the licensing authority may forthwith suspend the licence or certificate until that 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 Part of these Regulations called "the revoked regulations") are hereby revoked:—

(a) The Medicines (Fees Relating to Medicinal Products for Human Use) Regulations 1989(**7**);

(b) The Medicines (Fees Relating to Medicinal Products for Human Use) Amendment Regulations 1990(**8**); and

(c) The Medicines (Fees Relating to Medicinal Products for Human Use) Amendment (No. 2) Regulations 1990(**9**).

(**7**) S.I. 1989/418.
(**8**) S.I. 1990/210.
(**9**) S.I. 1990/2326.

(2) Paragraph (1) shall not affect—

(a) any 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 shall not apply in connection with any application made before the date on which these Regulations come into force.

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

(a) to any licence in respect of which the licensing authority has received 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.

(3) Where a fee was payable under the revoked regulations in connection with an application made before the date on which these Regulations come into force for the renewal of a licence, except a manufacturer's licence of the type referred to in regulation 11(1), which is due to expire on or after that date, the fee shall be refunded or, if it has not yet been paid, shall be waived; but this paragraph does not apply to any increase in such a fee which was payable under regulation 12 of the Medicines (Fees Relating to Medicinal Products for Human Use) Regulations 1989.

(4) Where a fee is payable in connection with an application made before the date on which these Regulations come into force for the renewal of a clinical trial certificate expiring on or after that date, the difference between the fee paid and the fee payable under regulation 10 shall be refunded or, if it has not yet been paid, that difference shall be waived but this paragraph does not apply to any increase in such a fee payable under regulation 12 of the Medicines (Fees Relating to Medicinal Products for Human Use) Regulations 1989.

William Waldegrave
26th June 1991 Secretary of State for Health

Signed by authority of the Secretary of State for Wales.

Nicholas Bennett
Parliamentary Under-Secretary of State, Welsh
26th June 1991 Office

Ian Lang
26th June 1991 Secretary of State for Scotland

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 27th June 1991.

Trumpington
Minister of State, Ministry of Agriculture,
Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 27th June 1991.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 27th June 1991.

W. J. Hodges
Permanent Secretary

We consent,

Sydney Chapman,
Greg Knight,
Two of the Lords Commissioners of Her
Majesty's Treasury

27th June 1991

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

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

PART I

INTERPRETATION

1. In this Schedule—

"active ingredient" means an ingredient of a medicinal product in respect of which therapeutic efficacy is claimed;

"complex application" means an application, other than a major application, for a product licence or, as the case may be, for a variation to a product licence where the application falls within one or more of the descriptions specified in sub-paragraphs (a) to (n) below:—

(a) the application is subject to the procedure laid down in Article 9 of Council Directive 75/ 319/EEC(**10**);

(b) 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;

(c) 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 product licence (other than a product licence of right) has previously been granted in the United Kingdom;

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

(e) the application relates to a medicinal product that is intended to be administered by a route of administation 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 product licence (other than a product licence of right) has previously been granted in the United Kingdom;

(f) 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 product licence (other than a product licence of right) has previously been granted in the United Kingdom;

(g) the application relates to a medicinal product which is a controlled release preparation except where—

  (i) the application is for a variation in connection with such preparation and does not relate to a matter mentioned in sub-paragraph (b), (c), (d), (f), (j), (k) or (n) of this definition or where the variation applied for does not affect the usage or formulation of the product; or

  (ii) the application is a simple application;

(h) 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

(**10**) O.J. No. L 147, 9.6.1975, p.13, as amended by Article 3 of Council Directive 83/570/EEC, O.J. No. L 332, 28.11.1983, p.1.

product which contains the same active ingredient as the product in question and in respect of which a product licence (other than a product licence of right) has previously been granted in the United Kingdom;

(i) 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 product licence (other than a product licence of right) has previously been granted in the United Kingdom;

(j) the application is an application to vary a product licence (parallel import) to include—

(i) importation of the same medicinal product bearing a marketing authorization issued in a different Member State of the European Economic Community; or

(ii) importation of a medicinal product which is differently formulated from any other medicinal product in respect of which a product licence (parallel import) has previously been granted in the United Kingdom;

(k) 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 product licence (other than a product licence of right) has previously been granted in the United Kingdom;

(l) 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 product licence which the applicant holds in respect of that product;

(m) the application is for the grant of a product licence 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 product licence which the applicant holds; or

(n) the application is to vary a product licence and relates to a change in the formulation of the medicinal product comprising one or more of the following—

(i) a change in the quantity of that product's active ingredient;

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

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

(iv) a change in two or more of that product's excipients other than to colours, or substances which are present only in trace amounts in the finished product.

"major application" means an application for a product licence in respect of 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 product licence (other than a product licence of right) has previously been granted in the United Kingdom;

"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 product licence (other than a product licence of right) has previously been granted in the United Kingdom, 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) as an approved ingredient or additive in food or in a food product;

"simple application" means an application for a product licence to which Article 4.8(a)(i) of Council Directive 65/65/EEC(**11**) applies other than one for a product licence for a medicinal product which is a new strength of a product in respect of which a product licence has previously been granted in the United Kingdom;

"standard application" means any application which is not a major, complex or simple application or an application for a product licence (parallel import).

PART II

CAPITAL FEES FOR APPLICATIONS FOR LICENCES AND CERTIFICATES

Product licences

1. Subject to paragraphs 2, 3, 4 and 5, the fee payable under regulation 4(a) in connection with an application for a product licence 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) in respect of any such application—	
	(a) (a) £17,000
(i) to which paragraph 5 of Chapter III of Part 3 of the Annex to Council Directive 75/318/EEC(**12**) applies; or	
(ii) which relates to an article or substance in relation to which Part II of the Act has effect by virtue of an order made under section 104 or 105(1)(a) of the Act;	
(b) (b) in any other case	(b) (b) £92,000
2. Complex application	**2.** £17,000
3. Standard application	**3.** £7,000
4. Simple application	**4.** £2,000
5. Application for a product licence (parallel import)	**5.** £1,750

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(**13**), the fee payable under regulation 4(a) in connection with an application for a product licence shall be £250.

3. 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 product licence 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.

(**11**) O.J. No. 22, 9.2.1965, p.369/65, as amended by Article 1.1 of Council Directive 87/21/EEC, O.J. No.L15/36, 17.1.1987.
(**12**) O.J. No. L147, 9.6. 1975, p 1.
(**13**) S.I. 1971/1267.

4.—(1) In this paragraph—

"joint development" means the development by two or more applicants for product licences 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 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 product licences have been received by the licensing authority within one month of each other;

"primary applicant" means that party to a joint development who first makes an application for a product licence relating to a new active ingredient which was the subject of that joint development; and

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

(2) Where a joint development relates to a medicinal product and an application for a product licence is submitted to the licensing authority by a secondary applicant, the fee payable under regulation 4(a) shall be—

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

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

(c) in respect of the first additional product licence 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 above, and in respect of any other such application by that secondary applicant, the amount payable in respect of a standard application under paragraph 1 above.

5.—(1) Subject to sub-paragraphs (2) and (3), where an application for a product licence (except an application by a secondary applicant within the meaning of paragraph 4) is for more than one such licence 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 above in respect of a separate application for each such licence.

(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 above plus—

(a) in respect of each additional product licence applied for which relates to a medicinal product of a different dosage form, the amount payable in respect of a complex application under paragraph 1 above; and

(b) in respect of each additional product licence 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 above plus—

(a) in respect of each additional product licence applied for which relates to a medicinal product of a different dosage form, the amount payable in respect of a complex application under paragraph 1 above; and

(b) in respect of each additional product licence 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 above.

Manufacturers' licences

6.—(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, £80;

(b) in any other case, £1,400.

(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, the sale or supply of which do not require a product licence and to which Article 2(2)(i)(e) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(**14**) applies.

Wholesale dealers' licences

7.—(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 £750.

(2) The fee payable under regulation 4(a) shall be £400 where an application for a wholesale dealer's licence relates to anything done in a registered pharmacy by or under the supervision of a pharmacist and amounts to wholesale dealing, where such dealing constitutes no more than 15% of the total turnover of the sale of licensed medicinal products carried on at that pharmacy.

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

Clinical trial certificates

8. The fee payable under regulation 4(a) in connection with an application for a clinical trial certificate shall be £17,000.

PART III

CAPITAL FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES AND CERTIFICATES

Product licences

1. Subject to paragraphs 2, 3, 4, 11 and 12, the fee payable under regulation 7(a) in connection with an application for variation of a product licence shall be—

(a) in the case of any complex application, £8,500; and

(b) in any other case, £280.

(**14**) S.I. 1971/1450.

2. Where a product licence has been granted in accordance with an application to which paragraph 5 of Chapter III of Part 3 of the Annex to Council Directive 75/318/EEC applies, the fee in connection with the first application for variation of that product licence made within 5 years of the date of the grant of that product licence, so as to authorise use of the medicinal product in a new therapeutic area, shall, in addition to the fee payable under regulation 7(a), be the difference between the fee paid in connection with the application for the grant of that licence and the fee which would have been payable had that application been a major application and the provisions of that paragraph had not applied.

3. The fee payable under regulation 7(a) in connection with an application for variation of a product licence (parallel import) which is a complex application, shall be the same as that payable in connection with an application for the grant of such a licence as specified in paragraph 1 of Part II of this Schedule.

4. The fee payable under regulation 7(a) in connection with an application for variation of a product licence shall be £80 in respect of each variation applied for which falls within one of the following paragraphs—

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

(b) a change of either or both of the name and the address of a manufacturer, assembler, storer or distributor named in the licence 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 from which distribution takes place;

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

(d) the removal from the licence of details of any of the activities to which the licence relates;

(e) the removal from the licence of details of any of the indications authorised for administration of the medicinal product;

(f) n relation to a product licence (parallel import), the removal from the licence of details of any of the medicinal products which the holder of the licence is authorised to import.

Manufacturers' licences

5. Subject to paragraphs 6 and 11, the fee payable under regulation 7(a) 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 6(2) of Part II of this Schedule, £80; and

(b) in any other case, £200.

6. The fee payable under regulation 7(a) in connection with an application for variation of a manufacturer’s licence shall be £80 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.

Wholesale dealers' licences

7. Subject to paragraphs 8 and 11, the fee payable under regulation 7(a) in connection with an application for variation of a wholesale dealer’s licence shall be £200.

8. The fee payable under regulation 7(a) in connection with an application for variation of a wholesale dealer’s licence shall be £80 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

9. Subject to paragraphs 10 and 11, the fee payable under regulation 7(a) in connection with an application for variation of a clinical trial certificate shall be £280.

10. 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(a) shall be £80.

Identical variations

11. Subject to paragraph 12 below, where more than one application is made at the same time by the same applicant for the variation of a product licence, 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(a)—

(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.

12. Where more than one complex application is made at the same time by the same applicant for the variation of a product licence, the fee payable under regulation 7(a)—

(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 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 not a complex application.

SCHEDULE 2

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

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 also 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.

Fees

2. Subject to paragraphs 3 to 5, 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) below—

(i) in respect of a minor inspection, £1,350;

(ii) in respect of a standard inspection, £2,700;

(iii) in respect of a major inspection, £5,100;

(iv) in respect of a supersite inspection, £10,200;

(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, £1,500;

(ii) in respect of a standard inspection, £5,500;

(iii) in respect of a major inspection, £8,500;

(iv) in respect of a supersite inspection, £17,000;

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

(i) in respect of a minor inspection, £500;

(ii) in respect of a standard inspection, £1,350;

(iii) in respect of a major inspection, £2,700;

(iv) in respect of a supersite inspection, £5,400;

(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 product licence and to which Article 2(2)(i)(e) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 applies, £100.

3.—(1) Subject to sub-paragraph (2), unless the applicant or, as the case may be, the holder of the licence establishes that an inspection is a minor inspection, standard inspection or a 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 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.

4. In the case of an inspection 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—

(a) except in a case falling within sub-paragraphs (b) and (c) below, £650;

(b) where 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) of the Act, £300;

(c) where the site relates to a registered pharmacy as referred to in paragraph 7(2) of Part II of Schedule 1, £300.

5. 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 reasonably incurred by him in respect of that inspection as a result of its being at a site outside the United Kingdom (such as interpreter's fees).

SCHEDULE 3

Regulation 14

PERIODIC FEES FOR LICENCES

PART I

INTERPRETATION

1. In this Schedule

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"new active substance" means a medicinal product which is not a limited use drug and which contains an active ingredient which has not previously been included as an active ingredient in a medicinal product in respect of which a product licence, other than a product licence of right, has been granted in the United Kingdom—

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

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

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

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

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

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

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

PART II

CALCULATION OF TURNOVER

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

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

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

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

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

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

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

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

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

PART III

PERIODIC FEES FOR LICENCES

Product licences

1.—(1) Subject to paragraphs 2 to 6 inclusive, the fee payable under regulation 14(3) in connection with the holding of a product licence relating to a medicinal product of a kind described in Column 1 of the following Table shall be the fee specified in the corresponding entry in Column 2 of that Table.

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

TABLE

Column 1 Kind of Product	Column 2 Fee Payable
1. New Active Substance	**1.** £10,000
2. Other kinds of Medicinal Product	(a) (a) £5,000
(a) Any product (not being a derivative of a new active substance) in respect of which a licence has been granted in consequence of a complex application submitted on or after 1st April 1989	

Column 1 Kind of Product	Column 2 Fee Payable
(b) (b) Prescription Only Medicine (i) Standard Fee	(b) (i) £900
(ii) Reduced Rate Fee	(b) (ii) £450
(iii) Maintenance Fee	(b) (iii) £150
(c) (c) Pharmacy Medicine (i) Standard Fee	(c) (i) £450
(ii) Reduced Rate Fee	(c) (ii) £225
(iii) Maintenance Fee	(c) (iii) £100
(d) (d) General Sales List Medicine (i) Standard Fee	(d) (i) £200
(ii) Reduced Rate Fee	(d) (ii) £100
(iii) Maintenance Fee	(d) (iii) £75
(e) (e) Herbal Product	(e) (e) £50
(f) (f) omoeopathic Product and Anthroposophic Product	(f) (f) £25

2. Notwithstanding the provisions of paragraph 1, in the case of an article or substance to which Part II of the Act applies by virtue of the Medicines (Surgical Materials) Order 1971(**15**) or the Medicines (Specified Articles and Substances) Order 1976(**16**), the fees payable under regulation 14(3) in connection with the holding of a product licence shall, where appropriate be—

(a) a standard fee of £250;

(b) a reduced rate fee of £125; or

(c) a maintenance fee of £80.

3. Subject to paragraph 4 below, where a licence is held in respect of a derivative of a new active substance, the fee payable under regulation 14(3) shall be—

(a) where it is of the same dosage form as, but of a different strength of active ingredient or different combination of active ingredients than, that relating to the new active substance, £3,000;

(b) where it is of a different dosage form to the new active substance, £5,000;

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

(2) Subject to sub-paragraphs (3) and (5) below, the appropriate periodic fee in respect of a derivative of a new active substance shall be payable for the five relevant licence fee periods following the licence fee period during which the product licence relating to the new active substance

(**15**) S.I. 1971/1267.
(**16**) S.I. 1976/968.

upon which the application was based, was first granted, or if the licence was granted before these Regulations came into force, until and including the relevant licence fee period during which falls the fifth anniversary of the date of granting of the licence.

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

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

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

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

(a) subject to paragraph 4(1) where turnover exceeds £200,000, that which would be payable if the drug were, respectively, a new active substance or a derivative of a new active substance;

(b) where turnover does not exceed £200,000, that payable in respect of a prescription only medicine in accordance with the Table set out in paragraph 1.

5. Where a product licence relates to any two or more of the kinds of medicinal product described in entries 2(b), (c) or (d) of the Table in paragraph 1 above, the fee payable under regulation 14(3) shall be in accordance with the lower of the fees specified as corresponding to those entries in Column 2 of that Table.

6. Where a reduced rate fee or a maintenance fee may be payable in respect of any relevant licence fee period and a licence holder does not submit evidence of turnover in relation to the relevant calendar year to the satisfaction of the licensing authority, the periodic fee payable by him shall, where applicable, be the standard fee for each description of medicinal product in respect of which a product licence is held by the licence holder.

Manufacturers' licences

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

Wholesale dealers' licences

8.—(1) Subject to sub-paragraph (2) and to paragraph 9, the fee payable under regulation 14(3) in connection with the holding of a wholesale dealer’s licence shall be £125.

(2) The fee payable under regulation 14(3) shall be £75 where–

(a) the wholesale dealer’s licence relates to anything done in a registered pharmacy by or under the supervision of a pharmist and amounts to wholesale dealing, where such dealing constitutes no more than 15% of the total turnover of the sale of licensed medicinal products carried on that pharmacy; or

(b) the wholesale dealer’s licence relates to general sales list medicines only.

9. Where in respect of any relevant licence fee period, the holder of a wholesale dealer’s licence does not submit evidence of turnover in relation to the relevant calendar year to the satisfaction of

the licensing authority, the periodic fee payable by him shall be the fee prescribed in paragraph 8(1) above.

PART IV

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

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

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

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 product licence for which the fee payable is that specified in entry 1(b) 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 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 an application to which paragraph 5 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;

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

4. 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.

5. In connection with an application for a product licence, 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

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 product licence 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.—(1) Subject to sub-paragraph (2), where an application for the grant of, or for a variation to, a product licence 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(a) 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) below 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) of the Act, 25%.

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

3. Where an application for the grant of, or 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(a) 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%.

4. 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.

5. In relation to a product licence (parallel import), the fee payable in respect of each such application shall be waived—

(a) where the licence relates to a medicinal product in respect of which a separate marketing authorisation has been granted pursuant to the provisions of Council Directive 65/65/EEC(**17**) in more than one Member State of the European Economic Community, those marketing authorisations are indicated on the product licence (parallel import) as having been validly granted in those Member States and the holder of that licence applies for

(**17**) O.J. No. 22, 9.2. 1965, p.369/65, as amended by Council Directives 75/319/EEC O.J. No.L147, 9.6. 1975, p.13, 83/570/EEC O.J. No.L332, 28.11. 1983, p.1, 87/21/EEC O.J. No. L15, 17.1. 1987, p.36 and 89/341/EEC O.J. No. L142, 25.5.1989, p.11.

the grant of a separate product licence (parallel import) in respect of each marketing authorisation which has been granted and so indicated; or

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

SCHEDULE 6

Regulation 19

ADJUSTMENT, REDUCTION OR REFUND OF PERIODIC FEES

1.—(1) Subject to sub-paragraphs (2) and (3) below, where a fee ("the renewal fee") has been paid on or after 1st April 1989 in connection with an application for the renewal of a licence, the periodic fee payable in respect of that licence shall be reduced—

(a) where the renewal fee was paid at the rate applicable after 1st April 1989 but before 5th March 1990, by the amount corresponding to 10% of the renewal fee which was paid, in respect of each of the first two relevant licence fee periods; and

(b) where the renewal fee was paid at either of the rates applicable after 5th March 1990 but before the date these Regulations come into force, by the amount corresponding to 25% of the renewal fee which was paid, in respect of each of the first two relevant licence fee periods.

(2) For the purposes of this paragraph the renewal fee does not include any increase in that fee which was payable under regulation 12 of the Medicines (Fees Relating to Medicinal Products for Human Use) Regulations 1989.

(3) The amount of the reduction referred to in sub-paragraph (1) above shall, where applicable, be rounded up to the next £1.

2. Where, after payment of any periodic fee payable in accordance with the provisions of these Regulations, the licence 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 licence, 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 licence up to the date of such surrender or revocation.

3. 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 which are to be payable under the Medicines Act 1971 in respect of licences and certificates relating to medicinal products for human use granted under the Medicines Act 1968.

Parts II, III and V and Schedules 1 and 2 provide for capital fees to be payable in respect of applications for, or variations to, product licences, manufacturers' licences, wholesale dealers' licences, clinical trial certificates and certificates permitting the export of medicinal products, and for associated inspections. All of these fees were provided for by the regulations revoked by these Regulations; the level of the fees has in most cases been reduced, but some remain unchanged and one has been increased.

Part VI of, and Schedule 3 to, the Regulations introduce a new fee, to be known as a periodic fee, which is payable in connection with the holding of product licences, manufacturers' licences and wholesale dealers' licences. The amount of the fee varies according to the type of product and, in some cases according to turnover. Fees which were previously payable in connection with renewals of licences have, with certain exceptions, been abolished. The exceptions are clinical trial certificates and certain manufacturers' licences (Part IV). Partial abatement of periodic fees has been provided for in respect of those applicants who have paid renewal fees since April 1989 (Schedule 6).

It is estimated that the changes made in the fee structure will result in a reduction of the yield from capital fees of about 35% so that in future those fees will provide about 60% of fee income, the other 40% being provided by periodic fees.

Regulation 23 contains transitional provisions. In particular it provides that any fee which was payable in respect of an application for the renewal of a licence which was due to expire after the date when these Regulations came into force but made before that date, shall be refunded or waived.

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 (Schedule 4).

Part VIII of the Regulations revokes the existing regulations relating to fees for medicinal products for human use.