STATUTORY INSTRUMENTS

1989 No. 418

MEDICINES

The Medicines (Fees Relating to Medicinal Products for Human Use) Regulations 1989

Made - - - -	*9th March 1989*
Laid before Parliament	*10th March 1989*
Coming into force - -	*1st April 1989*

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 the powers conferred by section 1(1) and (2) of the Medicines Act 1971(**1**) 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 (Fees Relating to Medicinal Products for Human Use) Regulations 1989 and shall come into force on 1st April 1989.

(2) Subject to paragraphs (3) and (4) below, these Regulations apply only to fees payable –

(**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 as extended to include regulations made under the Medicines Act 1971 by section 1(3)(b) of that latter Act.

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

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

(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 Medicines Act 1968 by an authority constituted under the National Health Service Act 1977(**4**), the National Health Service (Scotland) Act 1978(**5**) or the Health and Personal Social Services (Northern Ireland) Order 1972(**6**) or in respect of any inspection made in connection with such an application or during the currency of a licence or certificate held by such an authority.

(4) 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 Medicines Act 1968 where that application is made at the specific written invitation of the licensing authority.

Interpretation

2.—(1) Except as provided in paragraph (2) below, expressions used in these Regulations have the same meaning as in the Medicines Act 1968.

(2) In these Regulations, "medicinal product" includes any substance or article specified in any order made under section 104 or 105(1)(a) of the Medicines Act 1968 which directs that Part II of that Act shall have effect in relation to such substance or article.

PART II

FEES FOR APPLICATIONS FOR LICENCES OR CERTIFICATES AND FOR INSPECTIONS IN CONNECTION THEREWITH

Applications for Licences

3. Subject to regulations 16 and 20 of these Regulations, in connection with an application for a product licence, a manufacturer's licence or a wholesale dealer's licence there shall be payable by the applicant –

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

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

Applications for Clinical Trial Certificates

4. Subject to regulation 20 of these Regulations, in connection with an application for a clinical trial certificate, there shall be payable by the applicant a fee of £8,000.

(**4**) 1977 c. 49.
(**5**) 1978 c. 29.
(**6**) S.I. 1972/1265 (N.I.14).

Applications for certificates for exports of medicinal products

5.—(1) In connection with an application for a certificate issued under section 50 of the Medicines Act 1968, 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 £100;

(b) in any other case, a fee of £50; and

(c) in either case —

(i) a fee of £10 for each certified copy of the original certificate requested by the applicant in excess of four, and

(ii) a fee of £50 for each set of certificates requested by the applicant in addition to one.

(2) In paragraph (1)(c)(ii) above, "set of certificates" means the original certificate plus up to four certified copies of that certificate.

PART III

FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES OR CERTIFICATES

Variations of Licences

6. Subject to regulations 9, 16 and 20 of these Regulations, in connection with an application under section 30 of the Medicines Act 1968 for the variation of a provision of a product licence, a manufacturer's licence or a wholesale dealer's licence, there shall be payable by the applicant –

(a) the fee prescribed in Part III of Schedule 1 of these Regulations; and

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

Variations of Clinical Trial Certificates

7. Subject to regulations 8, 9 and 20 of these Regulations, in connection with an application under section 39(4) of the Medicines Act 1968 for variation of a provision of a clinical trial certificate, there shall be payable by the applicant a fee of £175.

Change of Name or Address in Clinical Trial Certificates

8. Where an application is made for a variation to a provision of the 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, there shall be payable by the applicant a fee of £50.

Applications for Multiple Variations

9. 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 except that no separate fee shall be payable in respect of any variation which is related to or is consequential upon another variation of a provision of the same licence or certificate which is applied for in the same application.

PART IV

FEES FOR APPLICATIONS FOR RENEWALS OF LICENCES OR CERTIFICATES

Renewal of Licences

10. Subject to regulations 12, 16 and 20 of these Regulations, in connection with an application under section 24(2) of the Medicines Act 1968 for renewal of a product licence, a manufacturer's licence or a wholesale dealer's licence, there shall be payable by the applicant —

(a) the appropriate fee prescribed in Part IV of Schedule 1 to these Regulations; and

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

Renewal of Certificates

11. Subject to regulations 12 and 20 of these Regulations, in connection with an application under section 38(2) of the Medicines Act 1968 for renewal of a clinical trial certificate there shall be payable by the applicant a fee of £2,000.

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

12. Where an applicant applies for renewal of a licence, or as the case may be, a clinical trial certificate so as to contain provisions which are not identical to that 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 made a separate application for each variation of that licence or certificate.

PART V

FEES FOR INSPECTIONS MADE DURING THE CURRENCY OF A LICENCE

13.—(1) Subject to paragraph (4) below and to regulations 16 and 20 of these Regulations, a fee in accordance with paragraphs 2 to 5 of Schedule 2 to these Regulations 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) The fee payable under paragraph (1) above 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 the manufacturer's or, as the case may be, the wholesale dealer's licence.

(3) Where a fee is payable under paragraph (1) above 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) 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 implemented.

PART VI

ADMINISTRATION

Payment of fees to Ministers

14. 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 Medicines Act 1968.

Time for payment of fees in connection with applications or inspections and refunds of such fees

15.—(1) Subject to paragraphs (2) and (3) below, all sums payable by way of fees under these Regulations in connection with any application shall be payable at the time of the application.

(2) If, following either the determination of an application or an inspection, 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.

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

Waiver, Reduction or Refund of Fees

16. The licensing authority shall waive payment of, reduce any fee or part of a fee otherwise payable under these Regulations or refund the whole or part of any fee already so paid in any of the circumstances specified in Schedule 3 to these Regulations.

Suspension of Licences

17. 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, 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

18. 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 VII

REVOCATION, SAVINGS AND TRANSITIONAL PROVISIONS

Revocation and Savings

19.—(1) Subject to paragraph (2) below, the Regulations specified in Schedule 4 to these Regulations are hereby revoked in so far as they apply in relation wholly or partly to medicinal products for human use.

(2) Paragraph (1) above shall not affect any notice given or any suspension made under the Regulations referred to in Schedule 4 to these Regulations and any such notice or suspension shall have effect as if given or made under these Regulations.

Transitional provisions

20.—(1) Subject to paragraphs (2) to (4) below, these Regulations shall not apply to any application made before 1st April 1989.

(2) A fee shall be payable in respect of any inspection made on or after 1st April 1989 in connection with any application made before that date as if these Regulations applied to that application.

(3) Where an application is made before 1st April 1989 to renew a licence or a certificate which is due to expire on or after 1st October 1989, a fee shall be payable in accordance with Part IV of these Regulations in connection with that application within 14 days following written notice from the licensing authority.

(4) In the case of an article or substance to which Part II of the Medicines Act 1968 applies by virtue of the Medicines (Surgical Materials) Order 1971(**7**), the fee payable under these Regulations in respect of an application for a product licence made on or before 31st March 1990 at the specific written invitation of the licensing authority shall be £250.

Signed by authority of the Secretary of State for Health

D. Mellor
Minister of State,
9th March 1989 Department of Health

Peter Walker
8th March 1989 Secretary of State for Wales

Malcolm Rifkind
8th March 1989 Secretary of State for Scotland

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

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 8th March 1989.

John MacGregor
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 9th March 1989.

F.A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 9th March 1989.

W.J. Hodges
Permanent Secretary

We consent,

Stephen Dorrell
Kenneth Carlisle
Two of the Lords Commissioners of Her Majesty's Treasury

7th March 1989

SCHEDULE 1 Regulations 3(a), 6(a) and 10(a)

FEES FOR APPLICATIONS, VARIATIONS AND RENEWALS OF LICENCES

PART I

INTERPRETATION

1. In this Schedule —

"active ingredient" means the ingredient of a medicinal product in respect of which ther peutic 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 —

(a) is subject to the procedure laid down in Article 9 of Council Directive 75/319/EEC(**8**)

(b) 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) 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) relates to a medicinal product containing a new excipient;

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

(f) 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) relates to a medicinal product which is a controlled release preparation;

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

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

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

(i) importation of the same medicinal product bearing a marketing authorisation 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; or

(k) 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;

"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;

"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; which has been granted a marketing authorisation in another Member State of the 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;

"simple application" means an application for a product licence to which Article 4.8(a)(i) of Council Directive 65/65/EEC(**9**) applies;

"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

FEES FOR APPLICATIONS FOR LICENCES

Product Licences

1. Subject to paragraphs 2 and 3 below, the fee payable under regulation 3(a) of these Regulations 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:

(**9**) 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. L 15/36, 17.1.1987.

Table

Column 1 Kind of Application	Column 2 Fee Payable
1. Major application —	
(a) (a) in respect of any such application —	1.(a) £8,000
(i) to which paragraph 5 of Chapter III of Part 3 of the Annex to Council Directive 75/318/EEC(**10**) applies, or	
(ii) which relates to an article or substance in relation to which Part II of the Medicines Act 1968 has effect by virtue of an order made under section 104 or 105(1)(a) of that Act;	
(b) (b) in any other case	1.(b) £40,000
2. Complex application	2. £6,000
3. Standard application	3. £3,000
4. Simple application	4. £1,50
5. Application for a product licence (parallel import) –	
(a) (a) in a case where –	5.(a) £1,500
(i) no such licence has previously been granted in the United Kingdom which is in respect of the same product bearing a marketing authorisation issued in the same Member State of the European Economic Community as the product for which a licence is applied; or	
(ii) the application relates to 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;	
(b) (b) in any other case.	5.(b) £1,000

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 product licence is applied for, the fee payable under regulation 3(a) of these Regulations in connection with that application shall be reduced by the amount of the fee paid in connection with the application for that certificate.

(**10**) O.J. No. L 147, 9.6.1975, page 1.

3.—(1) Subject to sub-paragraphs (2) and (3) below, where an application for a product licence 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 3(a) of these Regulations 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 above.

(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

4.—(1) The fee payable under regulation 3(a) of these Regulations in connection with an application for a manufacturer’s licence shall be —

(a) in a case to which sub-paragraph (2) below applies, £50;

(b) in any other case, £1,000; and

(c) in either case, if appropriate, a fee calculated in accordance with Schedule 2 to these Regulations in respect of any inspection made in connection with that application.

(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(**11**) applies.

Wholesale Dealers' Licences

5. The fee payable under regulation 3(a) of these Regulations in connection with an application for a wholesale dealer’s licence shall be £650.

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

PART III

FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES

Product Licences

1. Subject to paragraph 4 below, the fee payable under regulation 6(a) of these Regulations in connection with an application for variation of a product licence shall be —

(a) in the case of a complex application, £1,250; and

(b) in any other case, £175.

Manufacturers' Licences

2. Subject to paragraph 4 below the fee payable under Regulation 6(a) of these Regulations 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 4(2) of Part II of this Schedule, £50; and

(b) in any other case, £175.

Wholesale Dealers' Licences

3. Subject to paragraph 4 below, the fee payable under regulation 6(a) of these Regulations in connection with an application for variation of a wholesale dealer's licence shall be £175.

Other Variations

4. The fee payable under regulation 6(a) of these Regulations in connection with an application for variation of a product licence, a manufacturer's licence or a wholesale dealer's licence shall be £50 where —

(a) the variation applied for consists of no more than a change of either or both the name and the address of the holder of the licence; and

(b) in the case of an application for variation of a manufacturer's licence or a wholesale dealer's licence only, any change of address does not involve a change of the site of manufacture or wholesale dealing.

PART IV

FEES FOR APPLICATIONS FOR RENEWALS OF LICENCES

Product Licences

1. The fee payable under Regulation 10(a) of these Regulations in connection with an application for renewal of a product licence shall be —

(a) in the case of a product licence of right £100;

(b) in the case of a product licence (parallel import), £500;

(c) except in a case to which sub-paragraphs (a) or (b) above applies, where the medicinal product to which the product licence relates falls within a description or class of medicinal product specified in an Order under section 58(1) of the Medicines Act 1968, £750; and

(d) in any other case, £500.

Manufacturers' Licences

2. The fee payable under regulation 10(a) of these Regulations in connection with an application for renewal of a manufacturer's licence shall be —

(a) in the case of a manufacturer's licence referred to in paragraph 4(2) of Part II of this Schedule, £50;

(b) in any other case, £500.

Wholesale Dealers' Licences

3. The fee payable under regulation 10(a) of these Regulations in connection with an application for renewal of a wholesale dealer's licence shall be £325.

SCHEDULE 2

Regulations 3(b), 6(b), 10(b) and 13

FEES FOR INSPECTIONS

Interpretation

1.—(1) In this Schedule —

"major inspection" means an inspection at a site at which 60 or more 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.

(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 below, 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, £750;

(ii) in respect of a standard inspection, £1,500;

(iii) in respect of a major inspection, £3,000;

(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, £1,250;

(ii) in respect of a standard inspection, £2,500;

(iii) in respect of a major inspection, £5,000;

(c) except in the case of an inspection falling within sub-paragraph (b) above or sub-paragraph (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, £1,000;

(iii) in respect of a major inspection, £2,000;

(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, £50.

3.—(1) Subject to sub-paragraph (2) below, unless the applicant or, as the case may be, the holder of the licence establishes that an inspection is a minor inspection or a standard inspection, the fee payable shall be the appropriate fee specified in paragraph 2 above for a major 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 under these Regulations 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 under these Regulations shall be —

(a) except in a case falling within sub-paragraph (b) 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 Medicines Act 1968, £250.

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 16

WAIVER, REDUCTION OR REFUND OF 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 fees otherwise 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 shall be waived during that period or, if the period will, or is likely to, exceed 3 months, during the first 3 months of that period.

2.—(1) Subject to sub-paragraph (2) below, where an application for a product licence or a clinical trial certificate is withdrawn before determination by the licensing authority, the following percentage of the fee otherwise payable under regulation 3(a) or 4 of these Regulations 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 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 Medicines Act 1968, 25%.

(2) If an application for a product licence or 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 of the Medicines Act 1968 or by the Medicines Commission, no refund or waiver of the fee payable under regulation 3(a) or 4 of these Regulations in connection with that application shall be made under this paragraph.

3. Where an application for 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 3(a) of these Regulations 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, variation or renewal 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.

SCHEDULE 4

Regulation 19(1)

REGULATIONS REVOKED IN SO FAR AS THEY APPLY IN RELATION WHOLLY OR PARTLY TO MEDICINAL PRODUCTS FOR HUMAN USE

The Medicines (Fees) Regulations 1978(**12**)

The Medicines (Fees) Amendment Regulations 1979(**13**)

The Medicines (Fees) Amendment Regulations 1980(**14**)

The Medicines (Fees) Amendment (No. 2) Regulations 1980(**15**)

The Medicines (Fees) Amendment Regulations 1982(**16**)

The Medicines (Fees) Amendment Regulations 1983(**17**)

The Medicines (Fees) Amendment Regulations 1985(**18**)

(**12**) S.I. 1978/1121.
(**13**) S.I. 1979/899.
(**14**) S.I. 1980/16.
(**15**) S.I. 1980/1126.
(**16**) S.I. 1982/1121.
(**17**) S.I. 1983/1731.
(**18**) S.I. 1985/1231.

The Medicines (Fees) Amendment Regulations 1987(**19**)

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which replace the Medicines (Fees) Regulations 1978 (as amended), prescribe fees in connection with applications and inspections relating to licences and certificates granted under the Medicines Act 1968 in so far as they apply to medicinal products for human use only.

These Regulations provide for fees to be payable for applications for the grant of product licences, manufacturers' licences, wholesale dealers' licences, clinical trial certificates and export certificates (Part II).

The Regulations also provide for fees to be payable for applications for variations of such licences or certificates (Part III) and for renewal thereof (Part IV). In addition the Regulations provide for fees to be payable in respect of inspections of sites carried out in connection with such applications for such licences or certificates and during the currency thereof (Part V).

Administrative provisions (Part VI) deal with time of payment and waiver or refund of fees in specified circumstances.

Part VII of the Regulations deals with revocations, savings and transitional provisions.

(**19**) 1987/1439.