STATUTORY INSTRUMENTS

1991 No. 1474

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

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.

(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(**1**) 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

(**1**) 1968 c. 67.

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.

(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(**2**) 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

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

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 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(**3**); 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.

(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.

(**3**) 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.

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(**4**);

(b) The Medicines (Fees Relating to Medicinal Products for Human Use) Amendment Regulations 1990(**5**); and

(c) The Medicines (Fees Relating to Medicinal Products for Human Use) Amendment (No. 2) Regulations 1990(**6**).

(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.

(**4**) S.I. 1989/418.
(**5**) S.I. 1990/210.
(**6**) S.I. 1990/2326.

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