STATUTORY INSTRUMENTS

1989 No. 583

MEDICINES

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

Made - - - -	*30th March 1989*
Laid before Parliament	*3rd April 1989*
Coming into force - -	*24th 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 Animal Use) Regulations 1989 and shall come into force on 24th April 1989.

(2) 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 Act relating wholly or partly to medicinal products for animal 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; or

(c) in respect of samples submitted for testing in connection with applications for the grant, renewal or variation of, or during the currency of a product licence.

Interpretation

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

"the Act" means the Medicines Act 1968(**4**);

"annual fee" in relation to any product licence means the appropriate amount calculated in accordance with the provisions of Part II of Schedule 4;

"capital fee" means any fee (other than an annual fee) payable under the provisions of these Regulations;

"licence year" means the period beginning with the first day of April and ending with the last day of March of the year next ensuing;

"medicinal product" includes any substance or article specified in any Order made under (a) 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; or (b) section 130(3A) of the Act which provides that such substance or article shall, or shall not, be treated as a medicinal product.

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

PART II

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

Applications for Licences

3. Subject to regulations 22 and 24, 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 in connection with that application;

(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; and

(c) if appropriate, the fee prescribed in Part III of Schedule 1 in respect of samples submitted for testing at the request of the Licensing Authority in connection with that application.

Applications for Animal Test Certificates

4. Subject to regulation 24, in connection with an application for an animal test certificate, there shall be payable by the applicant a fee of £2,500.

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

Applications for certificates for exports of medicinal products

5.—(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 £100; or

(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) "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 AND FOR INSPECTIONS IN CONNECTION THEREWITH

Variations of Licences

6. Subject to regulations 8, 9, 22 and 24, 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, there shall be payable by the applicant–

(a) the fee prescribed in Part IV of Schedule 1; 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.

Variations of Animal Test Certificates

7.—(1) Subject to paragraph (2) and regulations 8, 9, 22 and 24, in connection with an application under section 39(4) of the Act for the variation of a provision of an animal test certificate, there shall be payable by the applicant a fee of £200.

(2) Where an application is made for a variation to a provision of the animal test 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

8. 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.

Variations at the Invitation of the Licensing Authority

9. Where an application for a variation is made at the express written invitation of the Licensing Authority, no fee shall be payable under this Part of these Regulations.

PART IV

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

Renewal of Licences

10. Subject to regulations 12, 22 and 24, in connection with an application under section 24(2) of the Act 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 V of Schedule 1; and

(b) in respect of any inspection of a description referred to in paragraph 1 of Schedule 2 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 24, in connection with an application under section 38(2) of the Act for renewal of an animal test certificate there shall be payable by the applicant a fee of £500.

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, an animal test 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) and to regulations 22 and 24, 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) 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 the manufacturer's licence or, as the case may be, the wholesale dealer's 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) 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

FEES FOR BATCH CONTROL TESTING DURING THE CURRENCY OF A LICENCE

14.—(1) A fee calculated in accordance with paragraph (2) shall be payable in respect of each product licence held, in which, as a condition of that licence there is a requirement that the licence holder shall submit for testing samples of each batch of the medicinal product which he has manufactured.

(2) During any licence year the fees referred to in paragraph (1) shall be–

(a) for the first sample and up to and including three samples, a fee of £600, payable by the licence holder at the time the first sample is submitted for testing;

(b) for four samples and up to and including ten samples, an additional fee of £200, payable by the licence holder at the time the fourth sample is submitted for testing;

(c) for ten samples or more, a further additional fee of £200 payable by the licence holder at the time the tenth sample is submitted for testing.

PART VII

ANNUAL FEES

Product Licences—annual fee

15.—(1) Subject to paragraph (3) and regulation 24 in connection with any application for the grant or renewal of any product licence there shall be payable by the applicant an annual fee in respect of each licence year during any part of which a product licence, granted or renewed in pursuance of the application is in force, or a product licence already held by the applicant, is in force, save that no annual fee shall be payable in respect of the licence year during which the last to expire of such product licences expires if that licence expires on a date earlier than the anniversary of that date on which that licence was granted which falls in that licence year.

(2) The annual fee shall be calculated in accordance with Schedule 4.

(3) The annual fee may be adjusted or refunded in any of the circumstances set out in Schedule 5.
PART VIII ADMINISTRATION

Payment of fees to Ministers

16. 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 Agriculture Ministers specified in section 1(1)(b) of the Act as appropriate.

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

17.—(1) Subject to paragraphs (2) and (3), 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) 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 or in respect of samples submitted for testing shall become payable within 14 days following written notice from the Licensing Authority.

Time for payment of annual fees

18.—(1) Subject to paragraphs (2) and (3), all annual fees shall be payable on 1st April of the licence year to which they relate: Provided that the annual fee payable under these Regulations for the licence year beginning 1st April 1989 shall not become payable until 1st September 1989.

(2) Subject to the proviso to paragraph (1), where an applicant first becomes liable to make any payment by way of annual fees of a particular kind during the course of a licence year, such fees shall be payable forthwith.

(3) Where an application is made by an applicant who has not previously held a product licence he shall be liable to pay a sum at the basic rate referred to in Part II of Schedule 4 at the time of the application in respect of the licence year in which the licence is granted.

Late payment of annual fees

19.—(1) Where an annual fee has not been paid by the holder or former holder of the licence by the end of the period of three months from the due date, a further fee, calculated in accordance with the provisions of the following paragraphs, shall be payable.

(2) The further fee referred to in the preceding paragraph shall be an amount equivalent to 1 per cent of the annual fee payable multiplied by the number of complete months contained in the period from the day after the end of the period of three months from the due date until the date when the annual fee is paid, rounded down to the nearest £10. Where the annual fee payable is less than £10, no such fee shall be payable.

(3) Where the holder or former holder of a licence has not furnished evidence of his annual turnover in accordance with the provisions of Part I of Schedule 4 so that the annual fee payable in respect of a licence year cannot be determined before the due date, he may make a payment of an amount on account of the annual fee payable by him (in this regulation referred to as a "payment on account").

(4) Where the holder or former holder of a licence has made a payment on account in the circumstances mentioned in the preceding paragraph the further fee payable by him shall be calculated as if in paragraph (2) above the reference to the annual fee payable were to the difference between the payment on account and the amount of the annual fee as subsequently determined.

(5) In this regulation–

(a) "due date" means the date upon which an annual fee became payable in accordance with the provisions of these Regulations;

(b) references to a period calculated from a day are references to the period inclusive of that day.

Suspension of Licences

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,

the said sum remains unpaid, the Licensing Authority may forthwith suspend the licence or certificate until such sum has been paid.

Civil proceedings to recover unpaid fees

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

Waiver, Reduction or Refund of Fees

22. The Licensing Authority may 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 exceptional circumstances or in any of the circumstances specified in Schedule 3.

PART IX

REVOCATION, SAVINGS AND TRANSITIONAL PROVISIONS

Revocation and Savings

23.—(1) Subject to paragraph (2), the Regulations specified in Schedule 6 are hereby revoked in so far as they apply in relation wholly or partly to medicinal products for animal use.

(2) Paragraph (1) shall not affect–

(a) any annual fee or part of such a fee under any of the Regulations specified in Schedule 6;

(b) any notice given or any suspension made under the Regulations specified in Schedule 6 and any such notice or suspension shall have effect as if given or made under these Regulations; and

(c) any proceedings constituted under the Regulations specified in Schedule 6 for the recovery of any fees due as debts due to the Crown.

Transitional provisions

24.—(1) Subject to paragraphs (2) and (3), these Regulations shall not apply to any application made before the date these Regulations come into force.

(2) A fee shall be payable in respect of any inspection made or any sample testing required after the date these Regulations come into force in connection with any application made before that date as if these Regulations applied to that application.

(3) Where an application is made before the date these Regulations come into force to review a licence or 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.

Kenneth Clarke
23rd March 1989 Secretary of State for Health

Peter Walker
20th March 1989 Secretary of State for Wales

Sanderson of Bowden
22nd March 1989 Minister of State, Scottish Office

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 19th March 1989.

L.S.

John MacGregor
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland 30th March 1989.

Zelma I. Davies
Under Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland 30th March 1989.

L.S.

J. C. Chalmers
Under Secretary

We consent,

Kenneth Carlisle
David Maclean
Two of the Lords Commissioners of Her
20th March 1989 Majesty's Treasury

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

CAPITAL 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 efficacy is claimed;

"biological medicinal product" includes an antigen, toxin, antitoxin, serum, antiserum or vaccine;

"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 17 of Council Directive 81/851/EEC(**5**) (notification to five or more Member States);

(b) relates to a medicinal product which is intended to be used in accordance with an indication for use in respect of a different species of animal or as treatment for a new medicinal purpose;

(c) relates to a medicinal product containing a new combination of active ingredients which have not previously been included in that combination in a medicinal product in respect of which a product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(d) relates to a medicinal product containing a new adjuvant or a new excipient;

(e) relates to a medicinal product which 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 for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

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

(g) 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 for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(h) relates to a biological medicinal product containing an active ingredient, the manufacture of which involves a growth substrate 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 has previously been granted in the United Kingdom;

(**5**) O.J. No. L317, 28.9.81 p.1.

(i) relates to a medicinal product which is a controlled release preparation and a product licence for animal use (other than a product licence of right) for such a preparation constituting the same active ingredient as the product in question has not previously been granted in the United Kingdom;

(j) 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 for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(k) names as manufacturer of the active ingredient of the medicinal product in question a different manufacturer from the manufacturer of the active ingredient of any medicinal product which contains the same active ingredient as the medicinal product in question and in respect of which a product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom; or

(l) relates to a biological medicinal product containing an active ingredient derived from a strain of micro-organism 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 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–

(a) an active ingredient that has not previously been included as an active ingredient in a medicinal product in respect of which a product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom; or

(b) an active ingredient in a medicinal product derived from genetically engineered micro-organisms, recombinant DNA technology or monoclonal antibodies; or

(c) in the case of a biological medicinal product, a vaccine of a particular micro-organism whether in a live or inactivated form, but this does not include a vaccine of a particular micro-organism which is derived from a strain of micro-organism which is antigenetically similar to that used in the manufacture of the active ingredient of a medicinal product in respect of which a product licence (not being 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 for animal use (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–

(i) in food or food products; or

(ii) in animal feedingstuffs where that product is intended for administration after being incorporated in the feedingstuff;

"simple application" means an application for a product licence when the application–

(a) is made by reference to an application for a particular product ("the existing product") in respect of which a product licence for animal use (other than a product licence of right) has previously been granted;

(b) is made by permission of the licence holder for the existing product;

(c) relates to a product which is in all the following respects the same as the existing product–

(i) it contains the same combination of active ingredients;

(ii) it is intended to be used in accordance with the same indications;

(iii) it is intended to be administered by the same route of administration;

(iv) the manufacturer named in the application is the same as the manufacturer of the existing product;

(v) the method of manufacture is the same;

(vi) in the case of a sterile product the method of sterilisation is the same and the container which is directly in contact with the product is made from the same material;

"standard application" means–

(d) any application in respect of a medicinal product for animal use specified in Annex 1 of Council Directive 70/524/EEC(**6**) or made pursuant to the Medicines (Exportation of Specified Veterinary Products) Order 1971(**7**), which is not a simple application;

(e) any other application which is not a major, complex or simple application.

PART II

capital fees for applications for licences

Product Licences

1. Subject to paragraph 2, the fee payable under regulation 3(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:

Column 1 Kind of application	Column 2 Appropriate Fee
1. Major application	**1.** £8,000
2. Complex application	**2.** £4,500
3. Standard application	**3.** £2,000
4. Simple application	**4.** £500

2. Where a major or a complex application is made by a person who is already the holder of an animal test 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) in connection with that application shall be reduced by the amount of the fee paid in connection with the application for that certificate.

(**6**) O.J. No. L270, 23.11.70 p. 1, as amended by Council Directive 84/587/EEC, O.J. No. L319, 8.12.84 p. 13.
(**7**) S.I. 1971/1309.

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

Manufacturers' Licences

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

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

(b) in any other case £1,000; and

(c) in either case, if appropriate, a fee calculated in accordance with Schedule 2 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–

(a) 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(**8**) applies; or

(b) emergency vaccines for use in poultry or other animals.

(3) For the purposes of sub-paragraph (2)(b) "emergency vaccines" means (a) no other suitable licensed vaccines are readily available for such use and (b) the vaccines are manufactured or assembled only from material obtained from the particular animal, flock or herd intended to be vaccinated.

Wholesale Dealers' Licences

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

(**8**) S.I. 1971/1450; the relevant amending instrument is S.I. 1972/1200.

PART III

capital fees for sample testing in connection with applications for licences

The fee payable under regulation 3(c) in respect of a sample requested by the Licensing Authority to be submitted for testing 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:

Column 1 Kind of application	Column 2 Appropriate Fee
1. Major application	**1.** £4,200
2. Complex application	**2.** £3,700
3. Standard application	**3.** £3,700
4. Simple application	**4.** £2,000

PART IV

fees for applications for variations of licences or certificates

Product Licences

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

(a) in the case of a complex application £600; and

(b) in any other case £200.

Manufacturers' Licences

2. Subject to paragraph 4, the fee payable under regulation 6(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 4(2) of Part II of this Schedule, £50;

(b) in any other case, £175.

Wholesale Dealers' Licences

3. Subject to paragraph 4, the fee payable under regulation 6(a) 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) 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 V

fees for applications for renewals of licences

Product Licences

1. The fee payable under regulation 10(a) in connection with an application for renewal of a product licence shall be £250.

Manufacturers' Licences

2. The fee payable under regulation 10(a) 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) in connection with an application for renewal of a wholesale dealer's licence shall be £325. 2Regulations 3(b), 6(b), 10(b) and 13FEES 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 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, £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–

(i) 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 applies; or

(ii) emergency vaccines for use in poultry or other animals;£50.

(e) For the purposes of sub-paragraph (d)(ii) "emergency vaccines" means (i) no other suitable licensed vaccines are readily available for such use and (ii) the vaccines are manufactured or assembled only from material obtained from the particular animal, flock or herd intended to be vaccinated.

3.—(1) Subject to paragraph (2), 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), £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 of such products specified in an Order made under section 51(1) of the Act, £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 22

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 animals will be, or is likely to be, put at risk, the Licensing Authority may decide that any fees otherwise payable under these Regulations–

(a) in connection with an application for the grant (variation or renewal) of a product licence relating to a medicinal product falling within that class or description; or

(b) in respect of any inspection made during the currency of such a licence

shall be waived during that particular period or, if the period will, or is likely to, exceed 3 months, during the first 3 months of that period.

2. The Licensing Authority may waive or reduce the payment of any capital fee payable under these Regulations in circumstances where–

(a) in its opinion the interests of human or animal health require a licence or certificate to be granted or an inspection to be made; and

(b) the medicinal product in respect of which an application for a licence or certificate has been made–

(i) is not intended for sale; or

(ii) is intended only for use in the treatment of rare conditions or in the treatment of a minor species of animal or as an emergency vaccine.

For the purposes of sub-paragraph (b)(ii) "emergency vaccine" means (i) no other suitable licensed vaccine is readily available and (ii) the vaccine is manufactured or assembled only from material obtained from the particular animal, flock or herd intended to be vaccinated.

3.—(1) Subject to sub-paragraphs (2) to (5), where the Licensing Authority–

(a) is satisfied that the annual turnover (as calculated in accordance with Part I of Schedule 4) of a medicinal product during any calendar year of the first five years of the currency of the product licence, has not exceeded, or is unlikely to exceed, £30,000; and

(b) is of the opinion that the interests of human or animal health require a product licence to be grantedany capital fee otherwise payable under these Regulations in connection with an application for a product licence or an inspection during the currency of that licence or a request to submit samples for testing, may be reduced or, if such a fee has already been paid, be refunded in part in proportion to the difference between the maximum turnover in any calendar year (during the first five years of the currency of the licence) and the sum of £30,000.

(2) Before a licence holder pays any reduced fee or receives any refund pursuant to sub-paragraph (1), he shall furnish evidence to the satisfaction of the Licensing Authority of the amount of annual turnover, in respect of the particular medicinal product, in each calendar year of the first five years of the currency of the licence.

(3) Where a reduced fee is determined in accordance with sub-paragraph (1) at the time of application on the basis of the estimated likely maximum turnover of the medicinal product during the first five years of the currency of the licence, any fee so determined shall be regarded as a provisional payment on account.

(4) Where a provisional payment on account is made in accordance with sub-paragraph (3) and subsequently the turnover in any calendar year in the first five years of the currency of the licence

exceeds £30,000, the licence holder shall be liable to pay the balance of the full fee otherwise payable under these Regulations.

(5) Where any provisional payment on account is made in accordance with sub-paragraph (3), the reduced fee shall be recalculated in accordance with the provisions of sub-paragraph (1) at the end of five years from the date of the grant of the licence and any difference between the fee so calculated and the provisional payment on account shall be payable by the applicant or, as the case may be, refunded to the applicant by the Licensing Authority.

4. Where an application for the grant or renewal of a product licence is made at the specific written request of the Licensing Authority any fee otherwise payable under these Regulations in connection with that application shall be waived.

5.—(1) Subject to sub-paragraph (2), where an application for a product licence is withdrawn before determination by the Licensing Authority, the following percentage of the fee otherwise payable (under regulation 3(a)) 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, 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 a product licence 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 Act or by the Medicines Commission, no refund or waiver of the fee payable (under regulation 3(a) of these Regulations) in connection with that application shall be made under this paragraph.

(3) 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 15

ANNUAL FEES FOR PRODUCT LICENCES

PART I

calculation of turnover

1. In relation to the calculation of turnover in any calendar year in accordance with the provisions of the succeeding paragraphs of this Part of this Schedule, "manufacturers' prices" shall mean, subject to the provisions of paragraph 2, the prices charged by manufacturers to wholesalers, except where medicinal products are supplied by manufacturers direct to retailers, in which case the prices charged by the licence holder may be reduced by such sum as, in the opinion of the Licensing Authority represents the difference between the prices paid by wholesalers and those normally charged by them to retailers according to the practice prevailing during the licence year in question with regard to such products.

2. Where a licence holder sells or supplies medicinal products which he has neither manufactured nor obtained from the manufacturer, in relation to the calculation of turnover in any calendar year in accordance with the provisions of the succeeding paragraphs of this Part of this Schedule "manufacturers' prices" shall mean the prices paid by, or on behalf of, the licence holder for those medicinal products.

3. For the purpose of calculating annual fees for product licences of a particular kind, "turnover" means the gross value at manufacturers' prices of all medicinal products sold or supplied by the applicant in the United Kingdom during the calendar year which ends 15 months before the end of a licence year. For the purposes of this paragraph medicinal products sold or supplied by the licence holder or applicant shall comprise only those products in respect of which a licence is held or for which application for a licence has been made.

(a) (a) For the purpose of satisfying the Licensing Authority for the purposes of Part II of this Schedule, an applicant shall state the amount of the turnover, calculated in accordance with the preceding paragraphs of this Part in respect of the calendar year which ends 15 months before the end of the licence year during which the application is made and in respect of each subsequent calendar year which ends 15 months before the end of any subsequent licence year during any part of which licences are held;

(b) 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. 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 such certificate the sum payable by way of fees for the licence year in question shall be calculated as provided for in paragraph 7 of Part II of this Schedule or shall be such lesser sum as the Licensing Authority shall specify in a notice served on the licence holder.

5. Where an applicant for a licence was not dealing in medicinal products during the calendar year which ends 15 months before the end of the licence year in which the application is made, but has taken over an existing business or concern, whether by purchase or merger or otherwise, the gross value of sales of that business or concern during the calendar year which ends 15 months before the end of the licence year in which the application is made may be treated as the gross value of sales for the purpose of calculating the turnover of that business or concern.

PART II

calculation of annual fees

1. Subject to the provisions of these Regulations annual fees shall be payable at the basic rate of £250 or 0.4% of turnover, whichever is the greater.

2. For the purpose of calculating annual turnover the provisions of Part I of this Schedule shall apply.

3. The amount payable by way of annual fees in accordance with this Schedule shall, when calculated on the basis of turnover, be rounded up to the nearest £10.

4. Where an application is made by an applicant who was not dealing in medicinal products during the calendar year which begins 15 months before the end of the licence year in which the application was made, he shall be liable to pay in respect of the year in which the licence is granted the sum of £250 until such time as the fee calculated in accordance with paragraph (1) is greater than that sum.

5. Where a licence holder has duly paid an annual fee of the appropriate kind at the rate applicable for any licence year, no additional annual fee shall be payable by that person for that year in respect of any application made earlier in that licence year.

6. Where applications are made on more than one occasion in the same licence year for product licences of the same kind, one annual fee only shall be payable which shall be regarded as having been paid in respect of all such applications made in that licence year.

7. Where in any licence year the licence holder does not submit evidence of turnover in relation to the relevant calendar year to the satisfaction of the Licensing Authority the annual fee payable by him in respect of that licence year shall be the sum of £10,000 together with an additional £2,000 for each description of medicinal product in respect of which a licence is held by the licence holder.

8. Where the holder of, or an applicant for a product licence is liable to pay an annual fee and his turnover for the purpose of calculating such a fee exceeds £30 million, one half of such turnover which is the excess of the said amount of £30 million shall be deducted from such turnover for the purpose of calculating the said annual fee.

PART III

lesser amounts of fees

1. Where the holder of a product licence sells or supplies emergency vaccines for use in poultry or other animals, the annual fee payable shall, instead of the amount otherwise payable under this Schedule, be 0.4% of turnover, calculated in accordance with paragraph 2 of Part I rounded up to the nearest £1, except that the minimum sum payable under this provision shall not be less than £10.

2. For the purposes of paragraph 1, "emergency vaccines" means (a) no other suitable licensed vaccines are readily available for such use and (b) the vaccines are manufactured or assembled only from material obtained from the particular animal, flock or herd intended to be vaccinated.

SCHEDULE 5

Regulation 15(3)

ADJUSTMENT OR REFUND OF ANNUAL FEES

1. Where an annual fee has been paid in accordance with these Regulations and the Licensing Authority is subsequently satisfied as to the gross value of sales in accordance with paragraph 4(a) of Part I of Schedule 4 the difference between the amount so paid and the annual fee so calculated may be refunded by the Licensing Authority.

2. Where, after payment of any annual fee payable in accordance with the provisions of these Regulations, the licence in respect of which such fee has been paid is revoked or expires on a date earlier than the date of expiry stated in the licence, the Licensing Authority may refund to the applicant the whole or any part of the difference between such annual fee as has been paid and the amount of the annual fee payable on the basis of the actual duration of the licence up to the date of such revocation or expiry.

3. In addition to the refunds (if any) payable under the provisions of the preceding paragraph, where the date of revocation or expiry as aforesaid is not an anniversary of the date on which the licence commenced and does not fall within a period of 3 months before any such anniversary, the Licensing Authority may refund to the applicant a sum equivalent to the fee for the appropriate portion of the licence year during which the said licence is not in force.

4. Where, after the payment of the whole or part of the fees in respect of a licence, the application is withdrawn before determination, the Licensing Authority may at the time of such withdrawal refund to the applicant the whole or any part of the fees paid.

5. Any sums payable to an 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.

SCHEDULE 6

Regulation 23(1)

REVOCATIONS

Regulations revoked	Reference
The Medicines (Fees) Regulations 1978	S.I.1978/1121
The Medicines (Fees) Amendment Regulations 1979	S.I. 1979/899
The Medicines (Fees) Amendment Regulations 1980	S.I. 1980/16
The Medicines (Fees) Amendment (No. 2) Regulations 1980	S.I. 1980/1126
The Medicines (Fees) Amendment Regulations 1982	S.I. 1982/1121
The Medicines (Fees) Amendment Regulations 1983	S.I. 1983/1731
The Medicines (Fees) Amendment Regulations 1985	S.I. 1985/1231
The Medicines (Fees) Amendment Regulations 1987	S.I. 1987/1439

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 animal use only.

The Regulations provide for increased fees to be payable for applications for the grant of product licences, manufacturers' licences, wholesale dealers' licences, animal test certificates and export certificates (Part II).

The Regulations also provide for increased fees to be payable for applications for variations of such licences or certificates (Part III) and for renewal thereof (Part IV). The Regulations provide for increased 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).

In addition the Regulations provide for increased annual fees to be payable, calculated on the basis of annual turnover, in connection with applications for the grant or renewal of any product licence (Part VII).

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

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

The only change of substance is the introduction of a fee to be payable in respect of the testing of samples where batch control sample testing is a condition of the licence (Part VI).