STATUTORY INSTRUMENTS

1978 No. 1121

MEDICINES

The Medicines (Fees) Regulations 1978

Made - - - -	31*st July* 1978
Laid before Parliament	10*th August* 1978
Coming into Operation	1*st September* 1978

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Scotland and in Wales, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, with the consent of the Treasury, in exercise of powers conferred by section 1(1) and (2) of the Medicines Act 1971**(a)** and now vested in them**(b)** 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 the following regulations, hereby make the following regulations:—

PART I

PRELIMINARY

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Fees) Regulations 1978 and shall come into operation on 1st September 1978.

(2) In these regulations, unless the context otherwise requires—

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

"annual fee" in relation to any licence described in column 1 of Table A means the appropriate amount set out in column 3 of that Table in relation to such licence;

"applicant", where the application is made on behalf of some other person, means the proposed holder of the licence or certificate;

"application" in relation to the grant, issue or renewal of any licence or certificate specified in Table A means an application made under and in accordance with regulations made under sections 18 and 36 of the Act which are for the time being in force, not being an application by an authority constituted under the National Health Service Act 1977**(d)**, the National Health Service (Scotland) Act 1972**(e)** or the Health and Personal Social Services (Northern Ireland) Order 1972**(f)**;

(a) 1971 c. 69.

(b) 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 (S.I. 1969/388) and, 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), and 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).

(c) 1968 c. 67.

(d) 1977 c. 49.

(e) 1972 c. 58.

(f) S.I. 1972/1256 (N.I. 14).

"calendar year" means the period of twelve months beginning with the first day of January in any year;

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

"imported proprietary product" means a proprietary medicinal product imported other than from a Member State of the European Community;

"licence holder" means a person to whom a licence of any kind required to be held under the Act has been granted, which licence has neither expired nor been revoked;

"licence year" means the period beginning with the first day of September in any year and ending with the last day of August of the year next ensuing;

"medicinal product" includes any substance or article specified in the Medicines (Surgical Materials) Order 1971**(a)**, in the Medicines (Control of Substances for Manufacture) Order 1971**(b)**, the Medicines (Dental Filling Substances) Order 1975**(c)**, the Medicines (Specified Articles and Substances) Order 1976**(d)**, or specified in any order made under section 104 or 105(1)(*a*) of the Act subsequent to the coming into operation of these regulations which directs that sections 7, 8, 31 or 32 of the Act shall have effect in relation to such substance or article as those sections have effect in relation to medicinal products within the meaning of the Act;

"the Minister" means one or other of the Ministers specified in paragraphs (*a*) and (*b*) of section 1(1) of the Act;

"of the same kind" in relation to two or more licences means that each of such licences is a licence described in the same paragraph of Table A and in relation to annual fees means that each of such fees is a fee described in the same paragraph of that Table;

"proprietary medicinal product" means

(*a*) a ready-prepared medicinal product placed on the market in the United Kingdom under a special name and in a special pack,

(*b*) for the purposes of paragraph (*a*) "medicinal product" does not include—

(i) vaccine, toxins or serums,

(ii) medicinal products based on human blood or blood constituents or radioactive isotopes,

(iii) homoeopathic medicinal products, or

(iv) veterinary drugs;

"relevant licence year" means any licence year during any part of which an applicant holds a product licence of the kind to which the application relates;

"standard amount" means the amount payable as the standard amount specified in column 2 of Table A;

"Standard Provisions Regulations" means the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971**(e)**, as amended **(f)**;

"Table A" means Table A set out in Part I of Schedule 1;

"Table B" means Table B set out in Part I of Schedule 1;

(a) S.I. 1971/1267.
(b) S.I. 1971/1200.
(c) S.I. 1975/533.
(d) S.I. 1976/968.
(e) S.I. 1971/972.
(f) The relevant amending instruments are S.I. 1972/1226, S.I. 1977/1053.

"wholesale dealers (import) licence" means a wholesale dealer's licence which relates to imported proprietary products and is subject to the provisions of paragraph 8 of Schedule 3 to the Standard Provisions Regulations;

and other expressions have the same meanings as in the Act.

(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 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.

(4) Except in so far as the context otherwise requires, any reference in these regulations to any provision of any enactment shall be construed as a reference to that provision as amended or extended by any enactment or instrument and as including a reference to any provision which may re-enact or replace it.

(5) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889**(a)** shall apply for the purposes of the interpretation of these regulations as they apply for the purposes of the interpretation of an Act of Parliament.

PART II

TYPES AND LEVELS OF FEES

Product licences

2.—(1) Subject to the following provisions of these regulations, in connection with any application for the grant or renewal of any product licence of a kind described in column 1 of Table A 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 of the same kind, 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 the date on which that licence was granted which falls in that licence year.

(2) The provisions of paragraph (1) shall not apply so as to impose any liability to pay an annual fee in respect of the grant or renewal of any product licence which relates to a product specified in paragraph 4 of Part II of Schedule 1.

(3) Subject to the following provisions of these regulations, in connection with an application for the grant of any product licence, there shall be payable by the applicant a capital fee in respect of each description of medicinal product to which the licence is to relate but only one such fee shall be payable for any application in respect of two or more medicinal products described in the same paragraph of Schedule 2.

(4) The provisions of paragraph (3) shall not apply so as to impose any liability to pay a capital fee in respect of the grant of a product licence in respect of any product specified in any paragraph of Part II of Schedule 1, other than any product specified in paragraph 5 or paragraph 9 thereof, if the applicant is already the holder of a product licence in respect of a medicinal product so specified in the same paragraph.

(a) 1889 c. 63.

(5) Subject to paragraph (3) above where an application for the grant of a product licence is in respect of two or more medicinal products having the same pharmaceutical form which consist of the same active ingredient in different strengths there shall be payable by the applicant a capital fee of the standard amount in respect of each different strength of the active ingredient in excess of one, in addition to any capital fee payable in accordance with the provisions of these regulations.

(6) Where, in connection with an application for the grant of a product licence, before the application is determined by the licensing authority the applicant notifies the authority that he desires to make a change in the particulars of the qualitative or quantitative composition of the medicinal product contained in the application, or to make a further change in such particulars, there shall be payable by the applicant a fee amounting to the standard amount in addition to any other capital fee.

(7) No capital fee shall be payable in respect of any application for a product licence, being a licence of right, in respect of any article or substance to which the Medicines (Dental Filling Substances) Order 1975**(a)** applies in cases where the article or substance in respect of which the application is made was on the market in the United Kingdom before 1st September 1971.

Renewal of product licences which are licences of right

3.—(1) In connection with any application for the renewal of a product licence which is a licence of right, except any such application as is made in the manner mentioned in paragraph (2) of this regulation, there shall be payable by the applicant, in addition to any other fee payable by virtue of any other provision of these regulations, a capital fee amounting to the standard amount in respect of each description of medicinal product to which such application relates.

(2) Where an application is made for the renewal for a further period of a product licence which is a licence of right on such form as may from time to time be approved by the licensing authority under regulation 2(2) of the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974**(b)** in respect of the further renewal of such product licence for medicinal products for human use or animal use respectively which have been renewed, there shall be payable by the applicant—

(i) where the licence was first renewed for the period of one year, a capital fee of £5,

(ii) where the licence was first renewed for the period of two years, a capital fee of £10,

(iii) where the licence was first renewed for the period of three years, a capital fee of £15,

(iv) where the licence was first renewed for the period of four years, a capital fee of £20,

in respect of each application in respect of medicinal products for human use or animal use respectively, without regard to the number of descriptions of medicinal products to which each application relates and where an applicant makes more than one application in respect of medicinal products for human use or animal use on such form as is mentioned in this paragraph on one or more occasions all such applications shall be deemed, for the purposes of this paragraph, to be a single application in respect of medicinal products for human use or animal use respectively on the said form.

(a) S.I. 1975/533. **(b)** S.I. 1974/832.

Manufacturers' licences and wholesale dealers' licences

4.—(1) Subject to the following provisions of these regulations, in connection with any application for the grant or renewal of any manufacturer's licence or wholesale dealer's licence described in column 1 of Table A, there shall be payable by the applicant an annual fee in respect of each licence year during any part of which a manufacturer's or wholesale dealer's licence granted or renewed in pursuance of the application is in force, or a manufacturer's or wholesale dealer's licence already held by the applicant is in force, except that no annual fee shall be payable in respect of the licence year during which the last to expire of such manufacturer's or wholesale dealer's licence expires if that licence expires on a date earlier than the anniversary of the date on which that licence was granted which falls in that licence year.

(2) Subject to the following provisions of these regulations, in connection with an application for the grant of any manufacturer's or wholesale dealer's licence, a capital fee shall be payable by the applicant in accordance with column 2 of Table A.

(3) No capital fee shall be payable in connection with an application for the renewal of any manufacturer's or wholesale dealer's licence unless additional premises are to be included in the licence as renewed, in which case the capital fee payable will be the amount shown as the basic rate in whichever of paragraphs 3(*a*), 3(*b*), 3(*c*), 4 or 5 of column 3 of Table A is appropriate in connection with such additional premises.

Clinical trial and animal test certificates

5. In connection with each application for the issue or renewal of a clinical trial certificate or animal test certificate described in column 1 of Table A, a capital fee shall be payable by the applicant in accordance with column 2 of paragraph 6 or, as the case may be, paragraph 7 of Table A.

Fees in respect of variations of licences for medicinal products other than certain specified articles or substances

6.—(1) In connection with an application for the variation of any product licence, manufacturer's licence or wholesale dealer's licence (other than a licence relating to an article or substance to which regulation 7 applies) fees shall be payable by way of capital fees as provided in the following paragraphs of this regulation unless such application is made at the specific invitation of the licensing authority.

(2) If an application is for the variation of a product licence and the variation relates to a change in the active ingredients, strength of the active ingredients, the pharmaceutical form or the indications for use of the medicinal product, there shall be payable by the applicant a capital fee amounting to the standard amount.

(3) In the preceding paragraph "change in strength" means—

(*a*) in relation to a medicinal product in the form of a tablet, capsule or other discrete article, an increase or decrease in the amount of the active ingredients in such tablet, capsule or other discrete article, and

(*b*) in relation to a medicinal product in any form other than a tablet, capsule or other discrete article, a change in the proportion of the active ingredient in the medicinal product.

(4) If an application is for the variation of a product licence to include a medicinal product of a description to which the licence does not relate, not being a medicinal product which has the same pharmaceutical form as a medicinal product already covered by the licence and consisting of the same active constituents in the same proportions, then the capital fee shall be equal to the capital fee which would be payable in respect of a separate application for a product licence in respect of the medicinal product to be added to the existing licence.

(5) If an application is for the variation of a product licence and a capital fee of the standard amount was payable (or a fee corresponding to that fee was payable under any of the revoked regulations) or no capital fee was payable in respect of the application for the grant of that licence, and in connection with an application for a licence in respect of the description of products to which the licence as varied would relate there would be payable the higher alternative amount, the capital fee shall be equal to the fee that would be payable if it were an application for the grant of a licence for that product.

(6) If an application is for the variation of a manufacturer's licence or of a wholesale dealer's licence where the variation to which the application relates includes the use of additional or different premises or the use of existing premises for a purpose which, had the application been for the grant of a licence, would have made the licence holder liable to pay a higher fee than that previously paid, then there shall be payable by the applicant a capital fee equal to the amount shown in whichever of paragraphs 3(*a*), 3(*b*), 3(*c*) or 5 of column 3 of Table A is appropriate.

(7) If an application is for the variation of a manufacturer's licence to authorise the manufacture of categories of products additional to those to which the licence relates, then there shall be payable by the applicant a capital fee equal to the amount shown as the basic rate in column 3 of paragraph 3 of Table A.

(8) If an application is for the variation of a wholesale dealer's (import) licence and the variation relates to—

(*a*) anything done or to be done in relation to an imported proprietary product, or

(*b*) naming in the licence the person who is to act as a qualified person for the purposes of paragraph 8 of Schedule 3 to the Standard Provisions Regulations,

there shall be payable by the applicant a capital fee equal to the amount shown as the basic rate in column 3 of paragraph 4 of Table A.

(9) In addition to the fees (if any) payable in accordance with the preceding paragraphs, on an application for the variation of a product licence or wholesale dealer's (import) licence or a manufacturer's licence, annual fees shall become payable as if the application had been an application for the grant of a licence as so varied.

Fees in respect of variations of licences for certain specified articles or substances

7.—(1) In connection with an application for the variation of any licence under Part II of the Act relating to any of the following articles or substances, fees shall be payable by way of capital fees as provided in the following paragraphs of this regulation unless such application is made at the specific invitation of the licensing authority.

(2) If an application is made for the variation of a product licence for a contact lens fluid and the variation relates to—

(*a*) a change in the indications for use of that product, or

(*b*) a change in the formulation of the ingredients affecting the purpose for which that product is indicated,

a capital fee shall be payable amounting to the standard amount.

(3) If an application is made for the variation of a product licence for—

(*a*) a dental filling substance,

(*b*) a contact lens, or

(*c*) an intra-uterine contraceptive device,

a capital fee shall be payable amounting to the standard amount where such variation relates to a change in materials from which the product is wholly or mainly composed.

(4) In this regulation—

"contact lens" means any thin curved shell of glass, plastic or other hard or soft material intended for use by being applied to the human eyeball as a contact lens or any blank from which a contact lens is to be prepared;

"contact lens fluid" means any substance for use in cleaning, disinfecting, irrigating, lubricating, wetting or storing any contact lens or any fluid in which such lens is soaked or rinsed or any fluid used as a barrier between such lens and the human eyeball or any other substance used in connection with the use of such lens;

"dental filling substance" means any substance used or for use in dental surgery for filling dental cavities;

"intra-uterine contraceptive device" means any instrument, apparatus or appliance for use by being inserted in the uterus of a human being for the purpose of contraception.

Fees in respect of product licences which have been subject to review

8.—(1) Subject to the provisions of paragraph (2) below where, in connection with the review by the licensing authority of the safety, quality and efficacy of substances or articles in respect of which product licences granted under Part II of the Act are in force, advice has been given to the licensing authority by the appropriate committee in relation to a medicinal product of a description to which a product licence (in this regulation referred to as a "relevant licence") relates and an application is made—

(*a*) for the grant of a product licence relating to a medicinal product of the same description, and

(i) the relevant licence has expired under the provisions of section 24(1A)(**a**) of the Act, or

(ii) the applicant has requested the licensing authority to grant him a product licence in substitution for the relevant licence, or

(*b*) for the variation of the provisions of the relevant licence under section 30 of the Act in such manner that the provisions of the licence shall correspond with such advice given to the licensing authority in relation to the medicinal products, or

(**a**) Section 24(1A) was added by regulation 4(4) of the Medicines (Medicines Act 1968 Amendment) Regulations 1977 (S.I. 1977/1050) and regulation 4(4) of the Medicines (Medicines Act 1968 Amendment) Regulations (Northern Ireland) 1977 (S.R. 1977 No. 170).

(*c*) for the first renewal of the relevant licence following the giving of such advice, except in relation to the renewal of a licence which has been granted or varied in the circumstances mentioned in sub-paragraph (*a*) or sub-paragraph (*b*) above,

there shall be payable by the applicant a capital fee amounting to the standard amount in respect of—

(i) each description of a medicinal product to which the licence is to relate, and

(ii) where the application is in respect of two or more medicinal products which consist of the same active ingredient in different strengths, each different strength of the active ingredient and, where any capital fee or any fee in connection with an application for variation would otherwise by payable by him in accordance with the provisions of these regulations, in substitution for such fee, provided that only one capital fee shall be payable in respect of any application in respect of two or more medicinal products described in the same paragraph of Schedule 2.

(2) Where the applicant has previously paid a capital fee amounting to the standard amount in accordance with the provisions of these regulations he shall not be liable to pay a further capital fee in accordance with the provisions of paragraph (1) above.

(3) Where the applicant has paid a capital fee of an amount less than the standard amount in accordance with these regulations, or in accordance with regulations in force at the time when such a fee became payable, the fee payable by him shall be an amount equal to the difference between the standard amount and the amount of the capital fee paid by him.

Change of responsibility

9.—(1) Where an application for the grant of a product licence is in respect of dealings in medicinal products for which a product licence has been granted to a person other than the applicant and the rights to carry on such dealings have been assigned to the applicant, the capital fee payable in connection with such application shall be the lower alternative amount in respect of each description of medicinal product to which such product licence relates, provided that the duration of the licence applied for does not exceed the unexpired portion of the duration of the licence granted to that other person.

(2) Where an application for the grant of a product licence is in respect of dealings in medicinal products in respect of which a product licence has been granted to a person other than the applicant and the rights to carry on such dealings have been assigned to the applicant in respect of more than one description of medicinal product, the total sum payable by way of capital fees in respect of such assignment shall be equal to 0·25 per cent. (rounded down to the nearest £10) of the value of sales at manufacturer's prices of all such medicinal products imported, manufactured, sold or supplied in connection with the business, the rights to which have been assigned during the calendar year which ends 20 months before the end of the licence year in which the application is made, or during a period of 12 months ending in that calendar year, or the amount set out in column 2 of paragraph 1 of Table B, whichever is the lesser sum, if such sum is less than the fee payable under paragraph (1) except that the minimum sum payable under this regulation shall not be less than the lower alternative amount.

Inspection fees

10. Where an application is made for the grant, renewal or variation of any licence and such application involves consideration by the licensing authority of the suitability of premises on which, or in part of which, medicinal products to which the application relates are to be manufactured and those premises have not been specified for that purpose in any existing licence held by the applicant, a sum of the amount set out in column 2 of paragraph 2 of Table B, or such lesser sum as the Minister may determine, shall be payable by way of a capital fee.

Fees for export certificates

11.—(1) A capital fee of the amount set out in column 2 of paragraph 8 of Table A shall be payable by the applicant in connection with each application for a certificate to be issued under section 50 of the Act, unless the applicant has, during the licence year ending on 31st August in the year preceding the date of the application, paid fees in respect of licences amounting to the sum set out in column 2 of paragraph 3 of Table B or more.

(2) For the purpose of determining whether the amount mentioned in paragraph (1) of this regulation has been paid—

(*a*) any annual fee payable under the provisions of these regulations shall be regarded as having been paid in the licence year to which such fee relates,

(*b*) any annual fee paid under the provisions of any of the revoked regulations shall be regarded as having been paid in the licence year in which it fell due,

(*c*) where an applicant elected to pay a duration fee under the provisions of the Medicines (Fees) Regulations 1971**(a)** or to pay annual fees in respect of a period of five years under the provisions of the Medicines (Fees) Regulations 1975**(b)** then one fifth of any such sum shall be regarded as having been paid on each anniversary of the date on which the licence to which it relates was granted.

PART III

ADMINISTRATION OF FEES

Payment of fees to Ministers

12. Any sums which under the provisions of these regulations become payable by way of or on account of fees shall be paid to the Minister.

Time for payment of annual fees

13.—(1) Subject to paragraphs (2) and (3), all annual fees shall be payable on 1st September of the licence year to which they relate.

(2) 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 licence of that kind he shall be liable to pay a sum at the basic rate referred to in Table A and to pay the balance of the fee payable upon the grant of the licence,

(a) S.I. 1971/1449. **(b)** S.I. 1975/366.

or within 120 days from the day upon which the licensing authority received the application, except where—

(*a*) the licensing authority are not required to determine the application by virtue of the provisions of section 44(1) of the Act;

(*b*) the licensing authority have consulted the appropriate committee under section 20(3) of the Act and the committee's advice has not yet been notified to the applicant;

(*c*) the licensing authority have notified the applicant in accordance with section 21(5) of the Act, or given notice in accordance with section 22(2) of the Act that they refuse to grant the licence and the application has not been determined.

Time for payment of capital fees

14. All sums payable by way of capital fees shall become due for payment at the time of the application for the grant of a licence, or the issue of a certificate, or the variation of a licence, as the case may be.

Late payment of annual fees

15.—(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 V of Schedule 1 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 or a provisional payment in the circumstances mentioned in paragraph 4 of Schedule 3, 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, or the provisional payment, as the case may be, 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.

Refund, adjustment and set-off of fees

16. Any fee or part of a fee payable under the provisions of these regulations may be refunded, adjusted or set-off by the Minister in any of the circumstances set out in Schedule 3.

Suspension of licences

17. Where, after the grant of any licence described in column 1 of Table A, any sum due by way of or on account of any fee payable in accordance with the provisions of these regulations remains unpaid, the Minister may serve a notice on the holder of the licence requiring payment of the sum unpaid, and if after a period of one month or such longer period as the Minister may allow from the service of such notice the said sum remains unpaid, the licensing authority may forthwith suspend the licence and any other licence in respect of which a fee would have been payable (but for the provisions of Part IV of Schedule 1) until such sum has been paid.

Waiver or reduction of fees

18. The Minister may waive payment of or reduce any fee or part of a fee otherwise payable in accordance with any of the provisions of these regulations in any of the circumstances set out in Schedule 4.

Civil proceedings to recover unpaid fees

19. All unpaid sums due by way of or on account of any fees payable by virtue of the provisions of these regulations in respect of any licences or certificates shall be recoverable as debts due to the Crown.

PART IV

REVOCATION, SAVINGS AND TRANSITIONAL PROVISIONS

Revocation and Savings

20.—(1) The following regulations (in these regulations called "the revoked regulations") are hereby revoked:—

(*a*) The Medicines (Fees) Regulations 1976**(a)**;

(*b*) The Medicines (Fees) Amendment Regulations 1976**(b)**;

(*c*) The Medicines (Fees) Amendment Regulations 1977**(c)**;

(*d*) The Medicines (Fees) Amendment (No. 2) Regulations 1977**(d)**.

(2) Such revocation shall not affect—

(*a*) any fee or part of a fee paid or to be paid under any of the revoked regulations and any such fee or part of a fee shall be regarded as though it had been paid under those regulations or was to be paid under them except that no further fee shall be required until such time as that further fee would have become payable under any of the revoked regulations and any fee or part thereof to be paid under any of the revoked regulations shall be treated as due under these regulations;

(*b*) any notice given or any suspension made under any of the revoked regulations and any notice given or suspension thereunder made shall have effect as if given or made under these regulations;

(*c*) any proceedings instituted under any of the revoked regulations for the recovery of any fees due as debts due to the Crown.

(a) S.I. 1976/347.
(b) S.I. 1976/1145.
(c) S.I. 1977/1056.
(d) S.I. 1977/1374.

Transitional provisions

21.—(1) Notwithstanding the provisions of any regulations revoked by these regulations the fees payable by any licence holder for the licence year ending on 31st August 1979 or thereafter shall not exceed the amount that would otherwise be payable under these regulations.

(2) Where a licence holder satisfies the Minister under the provisions of paragraph 1 of Part VII of Schedule 1 to the Medicines (Fees) Regulations 1976**(a)** that the gross value of goods sold or services supplied was less than £20,000 for the calendar year in question, the provisions of the said paragraph 1 shall continue to apply to such a licence holder in respect of the same application, or any application for the renewal of a licence granted before 1st September 1978, for the licence years up to and including that ending on 31st August 1981.

(3) No annual fee shall be payable for any product licence relating to any article or substance specified in paragraph 8 or paragraph 9 of Part II of Schedule 1 in respect of the licence year ending on 31st August 1978.

David Ennals,
Secretary of State for Social Services.

14th July 1978.

John Morris,
Secretary of State for Wales.

19th July 1978.

Bruce Millan,
Secretary of State for Scotland.

20th July 1978.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 24th July 1978.

(L.S.)

John Silkin,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 25th day of July 1978.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 25th day of July 1978.

(L.S.)

W. H. Jack,
Deputy Secretary.

We consent,

T. E. Graham,
Peter Snape,
Two of the Lords Commissioners of Her Majesty's Treasury.

31st July 1978.

(a) S.I. 1976/347.

Regulations 1, 2, 4, 5, 6, 9, 10, 11

SCHEDULE 1

PART I

TABLE A

Column 1 Kind of licence or certificate	Column 2 Capital fees	Column 3 ANNUAL FEES		
		Basic rate	Standard percentage	Alternative percentage
1. Product licence (products for human use)	(*a*) *Higher alternative amount*—£2,500 or (*b*) *standard amount*—£150, if the product to which the application relates is a product specified in Part II or satisfies the conditions of Part III, or (*c*) *Lower alternative amount*—£25.	£125	0·24	(*a*) *First year* Licence year 1978/9: 1·0 Licence year 1979/80 and subsequent licence years: 1·25 (*b*) *Second or subsequent year:* 0·5 (Calculated in accordance with Parts IV, V and VI except in relation to an application to which Part VII applies.)
2. Product licence (products for veterinary use)	(*a*) *Higher alternative amount*—£2,500 or (*b*) *standard amount*—£150, if the product to which the application relates is a product specified in Part II or satisfies the conditions of Part III, or (*c*) *Lower alternative amount*—£25.	£125	0·24 (Calculated in accordance with Parts IV, V and VI except in relation to an application to which Part VII applies.)	(*a*) *First year* Licence year 1978/9:1·0 Licence year 1979/80 and subsequent licence years: 1·25 (*b*) *Second or subsequent year:* 0·5

Column 1 Kind of licence or certificate	Column 2 Capital fees	Column 3 ANNUAL FEES		
		Basic rate	Standard percentage	Alternative percentage
3. Manufacturer's licence	An amount equal to the basic rate as determined in column 3.	(*a*) £100 for each set of premises in which manufacturing operations are to be carried out under the terms of the licence and (*b*) £50 for each set of premises in which assembly (but not manufacturing operations) are to be carried out under the terms of the licence and (*c*) £10 for each set of premises in which medicinal products are to be stored for distribution under the terms of the licence except in respect of premises in which manufacturing or assembly operations are also to be carried out under the terms of the licence. (Subject to the provisions of Part VII.)	0·025 (Calculated in accordance with Parts IV, V and VI except in relation to an application to which Part VII applies.)	(*a*) *First year* Licence year 1978/9: 0·1 Licence year 1979/80 and subsequent licence years: 0·125 (*b*) *Second or subsequent years:* 0·05

4. Wholesale dealer's (import) licence	An amount equal to the basic rate as determined in column 3.	£50 for each separate set of premises in which any functions specified in paragraph 8(3) of Schedule 3 to the Standard Provisions Regulations are to be carried out in relation to imported proprietary products to which the licence relates, or £10 for each separate set of premises in which medicinal products to which the licence relates are or are to be stored, whichever amount is the greater.	0·025 (Calculated in accordance with Parts IV, V and VI expect in relation to an application to which Part VII applies.)	(*a*) *First year* Licence year 1978/9: 0·1 Licence year 1979/80 and subsequent licence years: 0·125. (*b*) *Second or subsequent* years: 0·05
5. Wholesale dealer's licence other than a wholesale dealer's (import) licence.	An amount equal to the basic rate as determined in column 3.	£10 for each separate set of premises in which medicinal products to which the licence relates are to be stored.	NIL	NIL
6. Clinical trial certificate	£150, except in relation to an application to which paragraph 3 of Part VII applies.	NIL	NIL	NIL
7. Animal test certificate	£150, except in relation to an application to which paragraph 4 of Part VII applies	NIL	NIL	NIL
8. Export certificate	£4	NIL	NIL	NIL

TABLE B

Column 1 Circumstance	Column 2 Amount of fee or maximum limit
1. Alternative amount of maximum fee payable upon change of responsibility for the purpose of regulation 9(2).	£12,500
2. Maximum level of inspection fee for the purpose of regulation 10.	£1,000
3. Amount of fees payable for the purpose of regulation 11(1).	£1,000

PART II

MEDICINAL PRODUCTS, SUBSTANCES OR ARTICLES SUBJECT TO STANDARD AMOUNT CAPITAL FEES FOR PRODUCT LICENCES

1. Any herbal remedy within the meaning of the Act where the product consists entirely of ingredients included in products on the market in the United Kingdom prior to 1st September 1971.

2. Any mother tincture, solution or trituration or any attenuation thereof prepared in accordance with the methods of homoeopathic medicine or similar system which is to be sold or supplied solely for use as a homoeopathic product without any written recommendation (whether by means of a labelled container or package, or leaflet or in any other way) as to the use of that product.

3. Any substance or article (not being an instrument, apparatus or appliance) which is to be manufactured, sold, supplied, imported or exported wholly or mainly for use in circumstances to which paragraph (1)(*b*) of section 130 of the Act applies as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose and which is a medicinal product only by virtue of its use as aforesaid.

4. Any substance or article for incorporation in an animal feeding stuff which by virtue of section 42 of the Act is treated as if such substance or article were a medicinal product.

5. Any substance or article specified in the Medicines (Surgical Materials) Order 1971**(a)**.

6. Any substance specified in the Medicines (Control of Substances for Manufacture) Order 1971**(b)**.

7. Any medicinal product being a preparation of allergen extracts for the treatment of allergies, or any medicinal product for testing for allergic responses to specific substances.

8. Any substances used or for use in dental surgery for filling dental cavities specified in the Medicines (Dental Filling Substances) Order 1975**(c)**.

9. Any article or substance specified in the Medicines (Specified Articles and Substances) Order 1976**(d)**.

PART III

CONDITIONS ATTACHED TO PAYMENT OF STANDARD AMOUNT OF CAPITAL FEES FOR PRODUCT LICENCES

1. That the medicinal product in respect of which the application is made consists of active ingredients each of which is an active ingredient of a particular medicinal product (hereinafter in this Part of this Schedule referred to as "the existing preparation") which is for use by being administered to one or more human beings or animals, and—

(*a*) that at the time of application for the grant of the product licence in respect of that medicinal product the applicant was the holder of, or an applicant for, a product licence in respect of the existing preparation, provided that no initial fee was payable in respect of that product licence by virtue of the provisions of regulation 3(2)(*a*), (*b*) or (*d*) of the Medicines (Fees) Regulations 1971(e), or if such fee was payable it was the higher initial fee, or a capital fee at the higher alternative amount, or

(*b*) that any patent granted in respect of the existing preparation under the Patents Act 1949**(f)**, or the Patents Act 1977**(g)**, has expired and,

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(a) S.I. 1971/1267.
(b) S.I. 1971/1200.
(c) S.I. 1975/533.
(d) S.I. 1976/968.
(e) S.I. 1971/1449.
(f) 1949 c. 87.
(g) 1977 c. 37.

(*c*) that any patent granted in accordance with sub-paragraph (*b*) above has ceased to have effect for the period of one year ending on the date of the application for the grant of the product licence, and

(*d*) that the existing preparation has been effectively on the market for a period commencing on a date before 1st September 1971 and ending on the date of the application.

2. That the following conditions are satisfied by both the medicinal product in respect of which the application is made and the existing preparation, namely—

(*a*) that both products are for use by being administered to one or more human beings or both are for use by being administered to animals, and

(*b*) that where the existing preparation has been supplied only through hospitals, health centres or medical, dental or veterinary practitioners, the medicinal product in respect of which the application is made is also only to be supplied or to be made available for supply as aforesaid, and

(*c*) that both products fall within the same category for the purpose of paragraph 3 of this Part of this Schedule, provided that the existing preparation shall not be regarded as falling within the same category where the product to which the application relates is so formulated as to secure that the active ingredients, or one or more of them, shall be released or absorbed in a substantially greater or lesser time than the same ingredients of the existing preparation.

3. The categories referred to in paragraph 2(*c*) above are as follows—

(*a*) products for use by being administered by injection or infusion or other direct introduction into blood or tissue,

(*b*) tablets for oral administration,

(*c*) capsules for oral administration,

(*d*) products for oral administration not falling within categories (*b*) and (*c*) above,

(*e*) products for administration to the eye,

(*f*) products for inhalation,

(*g*) products for topical administration,

(*h*) products for administration through a body cavity, other than any product falling within any of the categories above,

(*i*) products for administration in any other way.

4. Notwithstanding the conditions contained in paragraph 2(*c*) above, where paragraph 1(*a*) above applies and the existing preparation falls within a different category, such preparation shall be taken as satisfying the requirements if either an initial fee or capital fee has been paid in respect of the existing preparation at the higher rate in force at the time, or the agreement of the Committee on Safety of Drugs for it to be marketed, or clearance under the Veterinary Products Safety Precautions Scheme was obtained for it.

PART IV

ASSESSMENT OF FEES

1. For the purpose of calculating annual turnover the provisions of Part V of this Schedule shall apply.

2. If for any licence year the fee payable in connection with an application for the grant of a licence of a particular kind calculated in accordance with Parts V, VI and VII of this Schedule is such that, together with the amount of fees of that kind payable in respect of the same application in respect of earlier years, it equals or exceeds the fee determined in accordance with paragraph 2 of Part VI of this Schedule, then the amount payable shall be that fee reduced by the total amount paid by way of annual fees in such earlier years and no further annual fees shall be payable in respect of that application.

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

4. 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.

5. 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.

6. Where for the purpose of determining whether the amount of the annual fee payable exceeds the amounts referred to in paragraphs 2 and 3 of Part VI, it is necessary to ascertain the annual fee paid in an earlier licence year, the sum so paid to be taken into account in determining the total amount of fees paid shall be treated as a payment in respect of the earlier or earliest of the applications in respect of which annual fees fell to be paid in that licence year.

PART V

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 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 Minister, 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. 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 by the applicant in the United Kingdom during the calendar year which ends 20 months before the end of a licence year. For the purposes of this paragraph medicinal products sold by the applicant shall comprise only those products in respect of which a licence is held or for which application for a licence has been made and shall not be regarded as including—

(*a*) any medicinal product, substance or article specified in paragraph 3 and 4 of Part II of this Schedule, or

(*b*) in the case of products for human use, any products which would be exempt under the provisions of the Medicines (Exemption from Licences) (Foods and Cosmetics) Order 1971**(a)**, as amended **(b)**, but are subject to licensing under the Act solely by reason that paragraph (3) of Article 2 of that Order is applicable to them.

3. Subject to the provisions of paragraph 4, for the purpose of calculating annual fees for manufacturers' licences, "turnover" means the gross value at manufacturers' prices of all medicinal products manufactured or assembled by the applicant during the calendar year which ends 20 months before the end of a licence year. For the purposes of this paragraph, medicinal products shall comprise only those products the manufacture or assembly of which is subject to a product licence or in respect of which an application has been made, with the exception of any medicinal product the manufacture or assembly of which is exempted from the restrictions imposed by section 8 of the Act by virtue of an exemption conferred by or under the provisions of sections 9 to 15 inclusive of the Act.

(a) S.I. 1971/1410. **(b)** S.I. 1973/2079.

4. (*a*) Where the licence is a manufacturer's licence and the licence holder's activities include the manufacture of products which are to be assembled by another licence holder, or the assembly of products manufactured by another licence holder, then—

(i) if the products are sold in order that they may be assembled by another licence holder, the value of the products as so sold shall be regarded as part of the manufacturer's turnover and the difference in the value of the products sold to and their value as sold by the person who assembles them shall constitute the assembler's turnover, or

(ii) if the products are assembled under contract, for the purpose of assessing fees the charge made for such assembly under the contract shall be included in the turnover of the person who assembles such products, and the amount of such charge shall be deducted from the manufacturer's turnover.

(*b*) Where the manufacturing activity consists solely of applying a process of sterilisation under contract for some other manufacturer, for the purpose of assessing fees, the charge made for such sterilisation shall be included in the turnover of the person who carries out such process, and this amount shall be deducted from that other manufacturer's turnover.

5. For the purpose of calculating annual fees for wholesale dealer's (import) licences "turnover" means the gross value at the prices paid by the applicant for imported proprietary products, except imported proprietary products which are in the possession of, or are handled by, the applicant in such circumstances as are mentioned in paragraph 8(7) or paragraph 8(8) of Schedule 3 to the Standard Provisions Regulations, which are distributed by him during the calendar year which ends 20 months before the end of a licence year.

6. (*a*) For the purpose of satisfying the Minister for the purposes of Part VI 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 20 months before the end of the licence year during which the application is made and in respect of each subsequent calendar year which ends 20 months before the end of any subsequent licence year during any part of which licences of that kind are held;

(*b*) where the licence holder fails to furnish evidence of the amount of annual turnover to the satisfaction of the Minister, the Minister 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 Minister 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 2 of Part VI of this Schedule or shall be such lesser sum as the Minister shall specify in a notice served on the licence holder.

7. Where particulars of the gross value of sales of medicinal products are not available to the applicant because he was not dealing in such products during the calendar year which begins 20 months before the end of the licence year in which the application is made, the provisions of paragraphs 1, 2, 3, 4 and 5 of this Part of this Schedule shall apply with the following modifications—

(*a*) where the applicant for a licence 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 20 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;

(*b*) in any other case, an estimate of the gross value of sales during the period of 12 months from the date on which dealings in medicinal products commenced may, if the Minister is satisfied, be treated as the turnover in the calendar year which ends 20 months before the end of the licence year in which the application is made for the purpose of calculating fees in accordance with Part VI of this Schedule, or for the purpose of making a provisional payment subject to adjustment in accordance with the provisions of paragraph 4 or paragraph 5 of Schedule 3, but not for the purpose of calculating the aggregate of the annual fees in accordance with paragraph 3 of Part VI of this Schedule.

8. The provisions of paragraph 7 of this Part of this Schedule shall apply in relation to wholesale dealer's (import) licences as if in paragraph 7 any references to the gross value of sales were references to the gross value at the prices paid by the applicant for imported proprietary products.

9. (*a*) For the purpose of calculating annual fees for product licences relating to any article or substance specified in paragraph 8 or paragraph 9 of Part II of this Schedule the turnover in any calendar year shall, subject to the provisions of sub-paragraph (2), be calculated by reference to the aggregate of the licence holder's turnover in medicinal products (including any articles or substances in relation to which an Order has been made under section 104 or section 105(1)(*a*) of the Act);

(*b*) turnover in respect of any calendar year for the purpose of this paragraph shall not include any turnover relating to any articles or substances specified in the said paragraph 8 or paragraph 9 of Part II unless on or before the last day of such calendar year, section 7 of the Act had application in respect of such article or substance.

PART VI

CALCULATION OF ANNUAL FEES

1.—(1) Subject to the provisions of these regulations, annual fees shall be payable at the basic rate or the standard percentage set out in column 3 of Table A, whichever is the greater, except in the following circumstances—

(*a*) in respect of the first year of the licence if no annual fee under either the Medicines (Fees) Regulations 1976**(a)** or these regulations has been paid in respect of such year, or

(*b*) in respect of the second or subsequent year of the licence unless the applicant is liable to pay an annual fee for the first year of a licence or has paid an amount equivalent to that fee as an advance payment in respect of an annual fee due upon the renewal of an existing licence.

(2) Where the circumstances set out in sub-paragraph (1)(*a*) or (*b*) apply, the applicant shall pay annual fees in accordance with the basic rate or the alternative percentage set out in column 3 of Table A, whichever is the greater.

2. 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 Minister, the annual fee payable by him in respect of that licence year shall be—

(i) where the licence is a product licence for a medicinal product for human use, the sum of £10,000, together with an additional £2,000 for each description of medicinal product in respect of which a licence of the same kind is held by the licence holder, or

(ii) where the licence is a product licence for a medicinal product for animal use, the sum of £10,000, together with an additional £2,000 for each description of medicinal product in respect of which a licence of the same kind is held by the licence holder, or

(iii) where the licence is a manufacturer's licence the sum of £20,000 together with £2,000 in respect of each set of premises in which manufacture or assembly is carried on, or

(iv) where the licence is a wholesale dealer's (import) licence the sum of £20,000 together with £2,000 in respect of each set of premises in which any functions specified in paragraph 8(3) of Schedule 3 to the Standard Provisions Regulations are to be carried out in relation to imported proprietary products to which the licence relates.

(a) S.I. 1976/347.

3.—(1) Where the licence holder does submit evidence of turnover in relation to the relevant calendar year before the licence year in which the application was made, the aggregate of the annual fees payable by the holder of the licence in respect of the whole of the period during which the licence is in force shall not exceed—

(*a*) where the licence is a product licence for a medicinal product for human use, a sum which is 3 per cent. of that turnover; or

(*b*) where the licence is a product licence for animal use, a sum which is 3 per cent. of that turnover; or

(*c*) where the licence is a manufacturer's licence or a wholesale dealer's (import) licence, a sum which is 0·3 per cent. of that turnover.

4. For the purpose of calculating annual fees under paragraphs 2 and 3, in any case where evidence of turnover is submitted for the first year, but not for subsequent years, the amount calculated under paragraph 3 above shall apply in any case if greater than that mentioned in paragraph 2.

5.—(1) Where a licence holder is liable to pay annual fees in respect of two or more of the following kinds of licences, namely—

(*a*) a product licence for a medicinal product for human use,

(*b*) a product licence for a medicinal product for animal use,

(*c*) a manufacturer's licence, or

(*d*) a wholesaler dealers' (import) licence,

and at least one of such fees is payable at the basic rate, the following provisions of this paragraph shall apply.

(2) Subject to sub-paragraph (3) below the amount payable by way of annual fees for the purposes of this paragraph shall be the higher of the following—

(*a*) 0·3 per cent. of the aggregate turnover under sub-paragraphs (1)(*a*) and (1)(*b*) above, or

(*b*) an amount equal to the standard amount.

(3) In any case to which this paragraph applies the abatement referred to in sub-paragraph (2) above shall be made as follows—

(*a*) firstly, against the fee that would otherwise be payable in respect of sub-paragraph (1)(*a*) above, but if this would reduce the fee that would otherwise be payable to less than £10, the fee payable for this purpose shall be £10;

(*b*) secondly, against the fee that would otherwise be payable in respect of sub-paragraph (1)(*c*) above, but if this would reduce the fee that would otherwise be payable to less than £10, the fee payable for this purpose shall be £10; and

(*c*) thirdly, against the fee that would otherwise be payable under sub-paragraph (1)(*d*) above.

(4) Where, for the purpose of this paragraph, the annual fee payable is reduced to the sum of £10 for each type of licence, no further abatement shall be made.

6. Where the holder of, or an applicant for a product licence of a particular kind is liable to pay an annual fee at the standard percentage and his turnover for the purpose of calculating such a fee exceeds £25 million, one half of such turnover which is in excess of the said amount of £25 million shall be deducted from such turnover for the purpose of calculating the said annual fee.

7. Where the Minister is satisfied that during the period from 1st September 1975 until the end of the licence year which immediately precedes the beginning of the licence year or for a period of five years (whichever is the less) in which an application is made—

(*a*) an applicant for the grant of a product licence has not, in the course of a business carried on by him, sold or supplied any medicinal product which was subject to the restrictions imposed by section 7 of the Act at the time of such sale or supply; or

(*b*) an applicant for the grant of a manufacturer's licence has not, in the course of a business carried on by him, manufactured or assembled any medicinal product which is subject to the restrictions imposed by section 8(2) of the Act; or

(*c*) an applicant for the grant of a wholesale dealer's licence has not, in the course of a business carried on by him, sold or offered for sale any medicinal product by way of wholesale dealing or distributed, otherwise than by way of sale, any proprietary medicinal product which is subject to the restrictions imposed by section 8(2) of the Act;

that applicant shall be treated as if he has paid an annual fee in respect of the licence year immediately preceding the year in which the application was made.

8. Where an applicant satisfies the Minister for the purposes of paragraph 7 above for some but not all of the period referred to the percentage of turnover payable by way of annual fees shall be increased to the standard percentage set out in column 3 of Table A multiplied by the number of years (not exceeding five) in respect of which the Minister is not so satisfied.

9.—(1) Any person who is the holder of a product licence may notify the licensing authority of his intention to apply for the renewal of that licence and at the time of such notification pay an amount equivalent to the annual fee which would have been payable if he had made an application for the renewal of that licence at that time.

(2) Any payment made by any person in accordance with the provisions of sub-paragraph (1) shall be refunded to that person upon request if he ceases to hold any licence of the kind to which his notification in accordance with the said sub-paragraph (1) relates and no liability for an annual fee of the same kind has arisen under the provisions of these regulations.

(3) If any payment made in accordance with sub-paragraph (1) exceeds the sum which would be payable under the provisions of these regulations if such payment had not been made such payment shall be treated as part payment on account of the first annual fee payable by virtue of these regulations.

PART VII

LESSER AMOUNTS OF FEES

1. Subject to paragraph 2 below where—

(*a*) the holder of a product licence or a manufacturer's licence sells or supplies medicinal products solely by retail or in circumstances amounting to retail sale (the products not being advertised), or

(*b*) a veterinary practitioner or veterinary surgeon manufactures or procures the manufacture of, medicinal products in circumstances to which section 9(3) of the Act applies,

the annual fee payable shall, instead of the amount otherwise payable under this Schedule, be 0·5 per cent. of turnover, calculated in accordance with paragraphs 2 or 3 of Part V rounded up to the nearest £1, except that the minimum sum payable under this provision shall not be less than £10.

2. Where a licence holder, in the circumstances set out in paragraph 1 above, holds more than one licence of a relevant kind and satisfies the Minister that the aggregate turnover as specified in paragraph 5(2)(*a*) of Part VI of this Schedule is less than £30,000, the amount payable in respect of annual fees shall be 0·5 per cent. of such turnover calculated as in paragraph 2 of Part V of this Schedule, rounded up to the nearest £1, except that the minimum sum payable under this provision shall not be less than £10 in respect of each kind of licence held, as specified in paragraph 5(1) of the said Part VI.

3. Where an application is made for a clinical trial certificate by a doctor or dentist by whom or under whose direction the medicinal product to which the certificate relates is to be administered and the conditions in Article 4(2)(iii) of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972**(a)**, as amended**(b)**, are satisfied, the capital fee payable shall be £1.

(a) S.I. 1972/1200. **(b)** S.I. 1974/498.

4. Where an application is made for an animal test certificate by a veterinary practitioner or veterinary surgeon by whom or under whose direction the medicinal product to which the certificate relates is to be administered and the conditions in Article 4(2)(iii) of the Medicines (Exemptions from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 are satisfied, the capital fee payable shall be £1.

5. Where a manufacturer's licence relates to manufacturing activity which—

(*a*) is limited to medicinal products to which Article 2 of the Medicines (Exemptions from Licences) (Special and Transitional Cases) Order 1971**(a)**, as amended **(b)**, applies and consists solely of mixing together medicinal products and ingredients, other than active ingredients, on premises of which the holder of the licence is the occupier and which he is able to close so as to exclude the public, or

(*b*) is limited to assembly only, where all the products to be assembled are for sale or supply in the course of a business and are supplied, without any recommendation, for the purpose of administration to a particular person after the holder of the licence has been requested by or on behalf of that person, and in that person's presence, to use his judgement as to the treatment required,

then the annual fee payable shall be the basic rate set out in column 3 of paragraph 3(*b*) of Table A.

Regulation 2(3)

SCHEDULE 2

Types of Medicinal Product for which only One Capital Fee is Payable

1. Medicinal products which have the same pharmaceutical form and either consist of the same single active constituent in different strengths, or consist of a mixture in different strengths of the same two or more active constituents in the same proportion.

2. Substances or articles having the same physical form and either having the same single active constituent in different strengths or being a mixture in different strengths of the same two or more active constituents in the same proportion.

3. Homoeopathic products and products using similar attenuations, in respect of—

(i) two or more attenuations of the same mother tincture or other solution of the same trituration, or

(ii) two or more attenuations of any mother tincture or other solution or trituration having the same specification and pharmaceutical form apart from the tincture, solution or trituration.

4. Medicinal products being preparations of allergen extracts for the treatment of allergies, in respect of two or more attenuations of the same allergen extract or of the same mixture of allergen extracts.

5. Medicinal products for testing for allergic responses to specific substances in respect of two or more allergen extracts manufactured by one and the same method, provided that the application states the substances from which the extracts are prepared.

Regulation 16

SCHEDULE 3

Circumstances in which Fees may be Refunded, Adjusted or Set-Off

1. If a sum greater than that payable under regulation 10 has already been paid by the applicant by way of inspection fees in respect of the application, then a sum equal to the difference between the sum so paid by the applicant and the sum payable under regulation 10 may be refunded by the Minister or, if the Minister so decides, treated as an advance payment in respect of any fee payable under any provision of these regulations.

(a) S.I. 1971/1450. **(b)** S.I. 1972/1200.

2. Where after payment of the whole or any part of any fees payable at the time of an application in accordance with the provisions of these regulations the licensing authority refuse to vary, grant or renew a licence or to issue or renew a certificate, as the case may be, the Minister may refund to the applicant the whole or any part of such fees paid.

3. Where the annual fee in respect of any licence year has been determined in accordance with the provisions of paragraph 7(*b*) of Part V of Schedule 1 on the basis of an estimate of the gross value of sales over a period of 12 months as therein provided and it appears to the Minister that such estimate is more than the actual gross value of sales during that period, the difference (if any) between the amount of the provisional payment made and the annual fee calculated on the basis of the actual gross value of sales may be refunded by the Minister.

4. Where the annual fee in respect of any licence year has been determined in accordance with the provisions of paragraph 7(*b*) of Part V of Schedule 1 on the basis of an estimate of the gross value of sales over a period of 12 months as therein provided and it appears to the Minister that such estimate is less than the actual gross value of sales during that period, the difference (if any) between the amount of the provisional payment made and the annual fee calculated on the basis of the actual gross value of sales shall thereupon become payable.

5. Where an annual fee has been paid in accordance with these regulations and the Minister is subsequently satisfied as to the gross value of sales in accordance with paragraph 6(*a*) of Part V of Schedule 1 or paragraphs 1 and 2 of Part VII of that Schedule, the difference between the amount so paid and the annual fee so calculated may be refunded by the Minister.

6. 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 Minister 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.

7. 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 Minister 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.

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

9. Any sums payable to an applicant by way of refund of any fees under the provisions of this regulation shall 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 4 Regulation 18

Reduction, Waiver or Refund of Fees

1. Where the Minister in an announcement published in the Gazette states that he is satisfied that the manufacture, sale or supply of medicinal products of any description specified in the announcement will be or is likely to be interrupted during any specific period, the Minister may decide that payment of such sums may be waived if the application is for the grant of a licence which relates to the sale, supply, importation or manufacture of such specified medicinal products during a period (not exceeding 3 months) within such specified period.

2. The Minister may waive payment of or reduce any sum otherwise payable by way of capital fees or, if such sum has been paid, refund it in whole or in part—

(*a*) in a case where a capital fee at the higher alternative amount is payable in respect of an application for the grant of a product licence for a medicinal product, having regard to the considerations that it is not intended to be sold or is intended only for use in the treatment of very rare conditions, or

(*b*) in a case where a clinical trial certificate or animal test certificate relates to a medicinal product which appears to the Minister to be unlikely to be of commercial value to the applicant, or

(*c*) in a case where the Minister is satisfied that the gross value of the sales of the medicinal product to which the application relates during any calendar year does not exceed a sum specified for that purpose by the Minister at the time of the application, or

(*d*) in a case where the medicinal product in respect of which the application is made consists of active ingredients each of which is an active ingredient of a particular medicinal product (in this paragraph referred to as "the existing preparation") which is for human use or animal use and—

(i) at the time of the application for the grant of a product licence a person other than the applicant was the holder of, or an applicant for the grant of, a product licence in respect of the existing preparation and the particulars relating to the medicinal product contained in the application are the same in all respects as the corresponding particulars contained in the application in respect of the existing preparation and a capital fee of the higher alternative amount was payable (or a fee corresponding to that fee was payable under any of the revoked regulations) in respect of the existing preparation, or

(ii) the existing preparation is for human use and the application is in respect of a medicinal product for animal use and the conditions set out in paragraph 1(*a*) or (*b*) and (*d*) of Part III of Schedule 1 are satisfied, or

(iii) where, as regards both the existing preparation and the medicinal product in respect of which the application is made, the conditions set out in paragraphs 1(*a*) or (*b*) and (*d*) and 2(*a*) of Part III of Schedule 1 are satisfied,

and the licensing authority are satisfied that the difference between the product in respect of which the application is made and the existing preparation is not sufficiently great to make it necessary to undertake the extent of scrutiny which would be appropriate for a product containing ingredients not present in any product already on the market and that the purpose for which the existing preparation may be recommended does not differ substantially from that of the product for which the application is made, or

(*e*) in a case where the medicinal product in respect of which the application is made consists of a mixture of two or more active ingredients, one of which is contained as an active ingredient in a medicinal product of a different description which satisfies the provisions contained in paragraphs 1(*a*) or (*b*) and (*d*) and 2 of Part III of Schedule 1, and the purpose for which such medicinal product may be recommended does not differ substantially from that of the product in respect of which the application is made and the licensing authority are satisfied that the difference between the products is not sufficiently great to make it necessary to undertake the extent of scrutiny which would be appropriate for a product containing ingredients not present in any product already on the market, or

(*f*) in a case where there is an application for a variation in respect of a change in the ingredients of the medicinal product by reason of—

(i) shortage of materials, or

(ii) any requirement imposed by any provision of any enactment or any regulation or order coming into force after the grant of the product licence.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations consolidate, with some modifications, the regulations prescribing fees payable in connection with certificates and licences granted under the Medicines Act 1968.

The Regulations provide for annual fees to be payable calculated on the basis of annual turnover, with certain exceptions for small businesses, and the payment of lump sums as capital fees.

Administrative provisions are also included in the regulations dealing with (inter alia) the time and method of payment of fees to Ministers; the refund, adjustment and set-off of fees; and the circumstances in which fees may be reduced or waived.

The Regulations also provide that the standard percentage for the purpose of calculating annual fees shall be 0·24 per cent. of turnover in respect of product licences held for products for either human or veterinary use.

The Regulations also contain transitional provisions, minor changes to facilitate their operation, and provisions consequential upon the extension of licensing to contact lenses, contact lens fluids and intra-uterine contraceptive devices.

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