STATUTORY INSTRUMENTS

1975 No. 366

MEDICINES

The Medicines (Fees) Regulations 1975

Made - - - -	12*th March* 1975
Laid before Parliament	24*th March* 1975
Coming into Operation	14*th April* 1975

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, with the consent of the Treasury, in exercise of powers under subsections (1) and (2) of section 1 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

GENERAL

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Fees) Regulations 1975 and shall come into operation on 14th April 1975.

(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 Part I of the Schedule means the amount specified in column 3 of that part of the Schedule, adjusted where appropriate under the provisions of regulation 8 and Parts IV and V of the Schedule, payable annually in respect of each fee period and includes preliminary fees and supplementary fees;

"the 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 of any licence or certificate specified in Part I of the Schedule means an application made under and in accordance

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(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; 1969 I, p. 1070) 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 paragraph 2(1)(b) of Schedule 1 to the Northern Ireland Act 1974 (c.28).

(c) 1968 c. 67.

with regulations made under sections 18 and 36 of the Act which are for the time being in force;

"corresponding fee periods" means fee periods that begin in the same calendar year;

"fee period" means the year beginning with the day on which any licence described in column 1 of Part I of the Schedule is granted and each subsequent year thereafter calculated from the anniversary of that date during any part of which the licence is in force;

"initial fee" in relation to any produce licence or certificate described in column 1 of Part I of the Schedule means the appropriate amount shown in column 2 in relation to such licence or certificate;

"preliminary fee" in relation to any licence described in column 1 of Part I of the Schedule means a single sum equal to the amount specified in column 3 of Part I of the Schedule as adjusted under the provisions of regulation 8 and Parts IV and V of the Schedule, to be paid at the time of application for the grant of the licence or as specified in regulation 12;

"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) or specified in any order made under section 104 or 105 of the Act subsequent to the coming into force of these regulations for the time being in force 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;

"retail pharmacist" means an applicant who is lawfully conducting a retail pharmacy business;

"retail pharmacist product" means any medicinal product in respect of which an application is made by a retail pharmacist and which is or is to be manufactured or assembled on premises at which his retail pharmacy business is conducted, or which is or is to be imported, solely for the purpose of sale (other than sale through the post) from premises at which that business is conducted;

"of the same kind" in relation to two or more licences means that each is a product licence, each a manufacturer's licence or each a wholesale dealer's licence, as the case may be;

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

(3) In these regulations any reference to a regulation or the Schedule shall be construed as a reference to a regulation contained in these regulations or, as the case may be, to the Schedule thereto, and any reference in a regulation or the Schedule to a paragraph shall be construed as a reference to a paragraph of that 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 or instrument 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(c) shall apply for the purposes of the interpretation of

(a) S.I. 1971/1267 (1971 II, p. 3632). (b) S.I. 1971/1200 (1971 II, p. 3506).
(c) 1889 c. 63.

these regulations as they apply for the purposes of the interpretation of an Act of Parliament.

Revocation and savings

2.—(1) The Medicines (Fees) Regulations 1971**(a)** (in these regulations called "the 1971 regulations") are hereby revoked.

(2)(*a*) Such revocation shall not affect any fee or any part of a fee paid or to be paid under the 1971 regulations and any such fee or part of a fee shall be regarded as though it had been paid under these 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 the 1971 regulations and any duration fee or part thereof paid under the 1971 regulations may be regarded as having been paid as an annual fee in respect of the appropriate fee period under these regulations and any fee or part thereof to be paid under the 1971 regulations shall be treated as due under these regulations.

(*b*) Where the fee which would be payable under these regulations amounts to a sum less than that actually paid under the 1971 regulations, then any difference between those sums may be refunded.

(3) Such revocation shall not affect any notice given or any suspension made under the 1971 regulations and any notice given or suspension made thereunder shall have effect as if given or made under these regulations.

(4) Such revocation shall not affect any proceedings instituted under the 1971 regulations for the recovery of any fees due as debts to the Crown.

PART II

FEES

Product licences

3.—(1) 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 an initial fee, a preliminary fee and an annual fee in respect of each fee period for which the licence is to remain in force.

(2) No initial fee or preliminary fee shall be payable in connection with an application for the renewal of any product licence.

(3) The provisions of paragraph (1) of this regulation shall not apply so as to impose any liability to pay an initial fee in respect of the grant of any product licence in respect of any medicinal product specified in any paragraph of Part II of the Schedule if the applicant is already the holder of a product licence in respect of a medicinal product so specified in the same paragraph.

Clinical trial and animal test certificates

4. In connection with each application for the issue of a clinical trial certificate or an animal test certificate an initial fee shall be payable by the applicant. No initial fee shall be payable in connection with an application for renewal of such certificates.

(a) S.I. 1971/1449 (1971 III, p. 4102).

Manufacturer's licence and wholesale dealer's licence

5.—(1) Subject to the following provisions of these regulations, in connection with each application for the grant of any manufacturer's licence or wholesale dealer's licence described in column 1 of Part I of the Schedule there shall be payable by the applicant a preliminary fee and an annual fee in respect of each fee period for which the licence is to remain in force.

(2) No preliminary fee shall be payable in connection with an application for the renewal of any manufacturer's licence.

(3) Subject to the following paragraphs of this regulation, there shall be payable in respect of an application for the grant of a manufacturer's licence made on or after 1st September 1973, or which was on that date under consideration by the licensing authority, an additional sum equal to the amount of the preliminary fee.

(4) The provisions of the preceding paragraph of this regulation shall not apply if the Minister is satisfied that, in the course of a business carried on by him, the applicant did not manufacture or assemble—

(*a*) medicinal products within the meaning of section 130(1)(*a*) of the Act, or

(*b*) substances or articles the manufacture or assembly of which is subject to the restrictions imposed by section 8 of the Act by virtue of the Medicines (Control of Substances for Manufacture) Order 1971 or the Medicines (Surgical Materials) Order 1971,

during the period between 1st September 1972 and the date of commencement of the licence referred to in paragraph (3) of this regulation, or that such manufacture or assembly during such period was exempt from the restrictions imposed by section 8 of the Act by virtue of an exemption granted by sections 8 to 12 or by an order under section 15 of the Act.

(5) The provisions of paragraph (3) of this regulation with the modification that the additional sum shall be twice the preliminary fee and the provisions of paragraph (4) of this regulation with the modification that the period therein referred to shall be the period between 1st September 1972 and 31st August 1973 shall apply with respect to any application for the grant of a manufacturer's licence made on or after 1st September 1974.

Variation fees

6.—(1) Except as provided in the following paragraphs of this regulation in connection with an application for the variation of any product licence, manufacturer's licence or wholesale dealer's licence described in column 1 of Part I of the Schedule there shall be payable by the applicant a variation fee of £5 for each application, unless that 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 licence as varied relates to any medicinal product specified in any paragraph of Part II of the Schedule, no variation fee shall be payable if the applicant is the holder of a product licence in respect of a medicinal product so specified in the same paragraph.

(3) 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 constituent in different strength or a mixture in different strengths of two or more active constituents in the same proportions, then the variation fee shall be equal to the initial fee (if any) 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.

(4) If an application is for the variation of a product licence and a lower initial fee (or no initial 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 initial fee, the variation fee shall be equal to the higher initial fee.

(5) Where no supplementary fee was payable in respect of the product licence to be varied and the product licence when so varied would be a licence falling within the descriptions of licences for which a supplementary fee is payable, there shall be payable in respect of such licence, from the date from which the licence is so varied, a supplementary fee of the amount specified in item 1(*c*) of Part I of the Schedule.

(6) If an application is for the variation of a manufacturer's or wholesale dealer's licence and, as a result of the variation, the licence falls into a different description of licence as set out in Part I of the Schedule, the annual fees payable shall be determined as if the first licence had been revoked on the date on which the variation came into effect and a new application had been made for a licence of the description of the licence as varied.

Change of responsibility

7.—(1) 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 dealing have been assigned to the applicant the initial fee payable in connection with such application shall be £5 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 such rights have been assigned in respect of more than one description of medicinal product, the total sum payable by way of initial fees in respect of such assignment shall be equal to 0·1 per cent of the value of sales at manufacturer's prices of all such medicinal products imported, manufactured, sold or supplied in connection with the business of the applicant during the second calendar year preceding the year in which the application is made or during a period of 12 months ending in that calendar year, or £2,500, whichever is the lesser sum, if such sum would be less than the fee payable under paragraph (1) above.

(3) For the purposes of these regulations where an application for the grant of a manufacturer's licence is in respect of manufacture or assembly of medicinal products in respect of which a manufacturer's licence has been granted to a person other than the applicant and the rights to carry on such manufacture or assembly have been assigned to the applicant, the rate of annual fee payable shall be the annual fee payable in respect of the existing licence, provided that the duration of the licence applied for does not exceed the unexpired period of the duration of the licence granted to that other person.

Annual and preliminary fees for applicants who are holders of or applicants for licences

8.—(1) Subject to the provisions of this regulation and of Part V of the Schedule, where two licences of the same kind are held by the same person for corresponding fee periods and, but for the provisions of this regulation, an annual fee would be payable in respect of each such licence, then only one annual fee shall be payable for such corresponding fee periods and

(*a*) if the amount of the annual fee in respect of each such licence is the same, the annual fee for the licence granted later shall not be payable, and

(*b*) if the amount of the annual fees in respect of such licences is not the same, the lesser of such fees shall not be payable.

(2) Where an applicant for a licence is the holder of a licence of the same kind as that applied for—

(*a*) if the annual fee for the licence already held is equal to or greater than the preliminary fee which would be payable on that application but for the provisions of this regulation, no preliminary fee shall be payable, and

(*b*) if the annual fee as aforesaid is less than the preliminary fee as aforesaid, that annual fee shall not be payable in respect of the fee period commencing in the calendar year in which that application is made.

(3) Where an applicant for a licence has previously paid a preliminary fee in respect of a licence which has not yet been granted but which is of the same kind as that applied for (hereinafter referred to as the "prior fee")—

(*a*) if that prior fee is equal to or greater than the preliminary fee that would be payable in respect of the application in question but for the provisions of this regulation, no preliminary fee shall be payable in respect of the application in question,

(*b*) if that prior fee is less than the preliminary fee as aforesaid, that prior fee shall be refundable.

(4) Where a licence is granted to a person who has paid a preliminary fee in respect of the application for that licence or in respect of an application for a licence of the same kind which has not been determined by the licensing authority, then

(*a*) if that preliminary fee is more than the first annual fee for the licence which has been granted, that annual fee shall not be payable, and

(*b*) if that preliminary fee is less than or equal to that annual fee the preliminary fee shall be refundable.

(5) Where an applicant for or holder of a licence ceases to be the applicant for or the holder of such licence, any fee that would have been payable but for the payment of a fee in connection with the application for such licence shall become payable forthwith.

(6) Where the holder of a manufacturer's licence is also the holder of a product licence and the annual fee payable in respect of that manufacturer's licence is less than the supplementary fee payable in respect of that product licence, the annual fee in respect of that manufacturer's licence shall not be payable.

PART III

PAYMENTS, INSTALMENTS, REFUNDS AND SUSPENSIONS

Payment of fees to Ministers

9. Any sums which under the provisions of these regulations become payable by way of or on account of any fees paid shall be paid to any of the Ministers specified in paragraphs (*a*) and (*b*) of section 1(1) of the Act (in these regulations referred to as "the Minister"), provided that if 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.

Time for payment of initial fees

10.—(1) Subject to paragraph (2) of this regulation all sums payable by way of initial fees shall become due for payment at the time of the application for the grant of a licence or certificate, as the case may be.

(2) An applicant for the grant of a product licence in respect of which the higher initial fee shown in column 2 of the Schedule is payable may pay the initial fee in two instalments as follows:—

(i) a first instalment of £150 payable at the time of making the application for that licence, and

(ii) a second instalment of the balance of the initial fee payable upon the grant of the licence or upon notice by the Minister given in accordance with regulation 12(5), whichever first occurs.

(3) Where any instalment payable hereunder in respect of any licence is not paid at the time for payment or within such other time as the Minister has allowed, the whole of the initial fee payable in respect of that licence shall thereupon become immediately payable and any further payment by instalments by the applicant under the provisions of this regulation shall only be made with the consent of the Minister.

Time for payment of annual fees

11.—(1) Subject to paragraph (2) of this regulation, all annual fees shall be payable on the day upon which a fee period commences, except that where regulation 8 is applicable, the day for payment of all annual fees for licences of the same kind shall be the day upon which a fee period commences for the licence which was first granted.

(2) The Minister may at any time before the grant of a licence require the applicant to pay the full amount of the fees in respect of that application.

Time for payment of preliminary fees

12.—(1) Subject to paragraph (2) of this regulation, all preliminary fees shall be payable at the time of application for the grant of a licence.

(2) An applicant for the grant of any licence to which paragraph 1(*c*) of the third column or paragraph 4 of Part I of the Schedule is applicable may in the circumstances described in paragraphs (3) or (4) of this regulation pay the preliminary fee by instalments as set out in those paragraphs.

(3) Where paragraph (2) of this regulation is applicable, unless at the time of application the applicant produces evidence or notifies the Minister that he proposes to produce evidence so as to satisfy the Minister in accordance with Part V of the Schedule, payment may be made by instalments as follows—

(*a*) a first instalment, payable at the time of application, of one half of the amount specified in Part I of the Schedule;

(*b*) a second instalment being the balance of such amount, payable upon the grant of the licence or upon notice by the Minister, given in accordance with paragraph (5) of this regulation, whichever first occurs.

(4) Where paragraph (2) of this regulation is applicable and the preliminary fee payable is more than £50 and the applicant produces evidence or notifies the Minister as aforesaid, payment may be made by instalments as follows:—

(*a*) a first instalment of £50, payable at the time of application;

(*b*) a second instalment, being the balance of the amount due, adjusted in accordance with Part V of the Schedule, payable upon the grant of the licence or upon notice by the Minister given in accordance with paragraph (5) of this regulation, whichever first occurs.

(5) Such notice by the Minister as is referred to in regulation 10(2)(ii) and in paragraphs 3(*b*) and 4(*b*) of this regulation may be served at any time after 120 days from the date of an application for the grant of a licence, 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) or given notice in accordance with section 22(2) of the Act that they propose to refuse to grant the licence and the application has not been determined.

Time for payment of variation fees

13. All variation fees shall be payable at the time of the application for variation.

Payment of estimate adjustment

14. Where the annual fee has been assessed on the basis of an estimate of the gross value of sales under the provisions of paragraph 8(*b*) of Part V of the Schedule and it is subsequently found that the estimate is less than the actual gross value of sales for that year, the difference (if any) between the annual fee payable calculated on that basis on the one hand and the annual fee calculated on the basis of the figure of the actual gross value of the sales on the other shall thereupon become payable.

Refund and set off of fees

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

(2)(*a*) Where the annual fees have been assessed on the basis of an estimate of the gross value of sales under the provisions of paragraph 8(*b*) of Part V of the Schedule and it is subsequently found that the estimate is more than the actual gross value of sales for that year, the difference between the annual fees calculated on that basis on the one hand and the annual fees calculated on the basis of the figure of the actual gross value of sales on the other hand or such part of the difference as may have been paid, may be refunded by the Minister.

(*b*) Where the amount of an annual fee has been paid at the rate specified in Part I of the Schedule and the Minister is subsequently satisfied as to the gross value of sales as set out in Part V of the Schedule the difference between the amount so paid and the annual fee so calculated may be refunded by the Minister.

(3) 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 day earlier than that stated on 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.

(4) 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 three months before any such anniversary the Minister may refund to the applicant the sum equivalent to the fee for the unexpired portion of the fee period calculated to the nearest 3 months.

(5) 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.

(6) 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.

Suspension of licences

16. Where after the grant of any licence described in column 1 of Part I of the Schedule, 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 regulation 8 until such sum has been paid.

PART IV

RECOVERY OF FEES

Civil proceedings to recover unpaid fees

17. 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.

Barbara Castle,
Secretary of State for Social Services.

19th February 1975.

John Morris,
Secretary of State for Wales.

24th February 1975.

William Ross,
Secretary of State for Scotland.

25th February 1975.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is herunto affixed on 27th February 1975.

(L.S.)

Frederick Peart,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 3rd day of March 1975.

(L.S.)

Norman Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 3rd day of March 1975.

(L.S.)

J. A. Young,
Permanent Secretary.

We consent.

T. Pendry,
M. Cocks,
Two of the Lords Commissioners of Her Majesty's Treasury.

12th March 1975.

Regulations 5, 6, 8, 12, 14, 16.

SCHEDULE

PART I

FEES

Kinds and descriptions of licences or certificates	Initial Fee	Annual Fees
1. Product licence	1. (*a*) £300 or, (*b*) £10, if the product to which the application relates is a product specified in Part II or satisfies the conditions set out in Part III of this Schedule.	1. (*a*) £10 or, (*b*) £2 in the case of a retail pharmacist product and (*c*) if the conditions specified in Part IV of this Schedule are satisfied, a supplementary fee of £200 or such lesser amount as may be appropriate under Part V of this Schedule.
2. Clinical trial certificate	2. (*a*) £25 or, (*b*) £1 where the applicant for a certificate is 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.	2. Nil
3. Animal test certificate	3. (*a*) £25, or (*b*) £1 where the applicant for that certificate is 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 (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 are satisfied.	3. Nil

(a) S.I. 1972/1200 (1972 II, p. 3553). **(b)** S.I. 1974/498 (1974 I, p. 1768).

Kinds and descriptions of licences or certificates	Initial Fee	Annual Fees
4. Manufacturer's licence in respect of the manufacture or manufacture and assembly of any medicinal product substance or article (other than a manufacturer's licence specified in entry No. 5 of this Schedule).	4. Nil	4. £2,500 or such lesser amount as may be appropriate under Part V of this Schedule.
5. Manufacturer's licence limited to the manufacture or manufacture and assembly of one or more of the medicinal products, substances or articles to which Article 2 of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(a), as amended (b) applies.	5. Nil	5. (*a*) £50 or, (*b*) £20 if the manufacturing activity consists solely of mixing together medicinal products and ingredients, other than active ingredients, 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 and (i) the products are manufactured and assembled on premises of which the holder is the occupier and which he is able to close so as to exclude the public, and (ii) the products are supplied without any written recommendation.

(a) S.I. 1971/1450 (1971 III, p. 4118). (b) S.I. 1972/1200 (1972 II, p. 3553).

Kinds and descriptions of licences or certificates	Initial Fee	Annual Fees
6. Manufacturer's licence in respect only of the assembly of any medicinal product.	6. Nil	6. (*a*) £50 or, (*b*) £20 when the medicinal products to which the licence relates are named in the licence and are assembled only for retail sale or supply from the premises where they are assembled in the course of the licence holder's business and are not advertised or, (*c*) £10 in the case of a retail pharmacist product, or where all the products to be assembled are for sale or supply in the course of a business and where the person carrying on the business sells or supplies the product without any written recommendation for administration to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgement as to the treatment required.
7. Wholesale dealer's licence, except where the applicant is also the holder of a manufacturer's licence.	7. Nil	7. £10.
8. Wholesale dealer's licence where the applicant is also the holder of a manufacturer's licence.	8. Nil	8. £5.

PART II

MEDICINAL PRODUCTS, SUBSTANCES OR ARTICLES SUBJECT TO LOWER INITIAL FEE FOR PRODUCT LICENCES

1. Any herbal remedy within the meaning of the Act.

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 for use 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 and 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)** and in the Medicines (Control of Substances for Manufacture) Order 1971**(b)**.

6. 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.

PART III

CONDITIONS ATTACHING TO PAYMENT OF LOWER INITIAL FEE 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 some other medicinal product or products (hereinafter in this Part of this Schedule referred to as "the existing preparations") which is for use by being administered to one or more human beings or animals, and either—

(*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 preparations, provided that either 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 1971 regulations, or if such fee was payable it was the higher initial fee, or

(*b*) that rights under the Patents Act 1949**(c)** do not apply to the existing preparations and that the existing preparations have been effectively on the market in the United Kingdom for a period of 5 years ending on the date of the application, that both that medicinal product and the existing preparations are for use by being administered to one or more human beings or, as the case may be, animals, and that in relation to the routes of administration of both that medicinal product and the existing preparations the conditions set out in paragraph 3 of this Part of this Schedule are satisfied.

2. In addition to the conditions contained in sub-paragraph (*b*) of the preceding paragraph, where the existing preparations have been supplied only through hospitals, health centres, or medical, dental or veterinary practitioners, that the medicinal product in respect of which the application is made is also only to be supplied or only to be available for supply as aforesaid.

(a) 1971/1267 (1971 II, p. 3632). **(b)** S.I. 1971/1200 (1971 II, p. 3506).
(c) 1949 c. 87.

3. The conditions to which paragraph 1 of this Part of this Schedule refers in relation to the routes of administration of both the medicinal product and the existing preparations are as follows:—

(i) if the existing preparations are for use by being administered by injection or infusion or other direct introduction into blood or tissue (hereinafter referred to as "route A"), the medicinal product must be a product for administration also by route A, or orally by or through the mouth (hereinafter referred to as "route B") or by or through any other body cavity (hereinafter referred to as "route C") or by some route other than route A, B or C (hereinafter referred to as "route D"); or

(ii) if the existing preparations are for use by being administered by route B, the medicinal product must be a product for administration also by route B or by route C or D; or

(iii) if the existing preparations are for use by being administered by route C, the medicinal product must be a product for administration also by route C or by route D; or

(iv) if the existing preparations are for use by being administered by route D, the medicinal product must be a product for administration also by route D.

PART IV

CONDITIONS ATTACHING TO PAYMENT OF THE SUPPLEMENTARY FEE

1. That the applicant either—

(*a*) is not the holder of a manufacturer's licence, or

(*b*) is the holder of a manufacturer's licence and the annual fee payable in respect of that licence is equal to or less than the supplementary fee which would be payable under these regulations if the applicant were not the holder of such manufacturer's licence.

2. That the application is in respect of a product licence of one of the three following descriptions, that is to say—

(*a*) a product licence which relates to any medicinal product that is or is to be manufactured outside the United Kingdom, or

(*b*) a product licence which comes within the provisions of subsection (4) of section 43 of the Act (extension of licensing requirements to certain special circumstances) other than such a product licence which relates to a retail pharmacist product, or

(*c*) a product licence which relates to any medicinal product that is manufactured in circumstances which enable such manufacture to be carried on otherwise than in accordance with a manufacturer's licence.

PART V

LESSER AMOUNTS OF ANNUAL FEES

1.—(*a*) Subject to the provisions of the succeeding sub-paragraphs, where the applicant for the grant or renewal of a manufacturer's licence specified in entry No. 4 in Part I of this Schedule satisfies the Minister that in the course of a business carried on by him during the second calendar year preceding the year in which the application is made or during a period of 12 months ending in that calendar year (either of which periods is hereinafter referred to as the "relevant year") the gross value of sales, calculated at manufacturer's prices, of all medicinal products manufactured by him in the United Kingdom was an amount less than £2,500,000, the rate of the annual fee payable shall, instead of £2,500 be a lesser rate equivalent to 0·1 per cent of that amount of the gross value of sales (reduced to the nearest multiple of £10) or £50 whichever is the greater; and where the manufacturing activity consists solely of applying a process of sterilization to medicinal products manufactured by some other

person under a manufacturer's licence other than that held by the person carrying out the sterilization, the value of the sales of such medicinal products shall for the purpose of this Part of this Schedule be the charge made for applying the process of sterilization.

(*b*) Where the applicant as aforesaid is a retail pharmacist and the product in respect of which the application is made is a retail pharmacist product and the applicant satisfies the Minister that the gross value of sales as aforesaid was an amount less than £10,000, then the rate of annual fee payable shall, instead of the lesser rate as aforesaid, be a lesser rate equivalent to 0·5 per cent of the amount of the gross value of sales (reduced to the nearest multiple of £5) or £5 whichever is the greater.

(*c*) Where the applicant for the grant or renewal of a manufacturer's licence satisfies the Minister that in the course of a business carried on by him during the second calendar year preceding the year in which the application is made or during a period of twelve months ending in that calendar year (either of which periods is hereinafter referred to as the "relevant year") the gross value of goods sold or supplied or services rendered (the value of the supply shall be taken to be the consideration received in respect thereof) was an amount less than £10,000, the annual fee payable shall instead of the amount that would otherwise have been payable under this Schedule be 0·5 per cent of that gross value or £5 whichever is the greater.

2.—(*a*) Subject to the provisions of the succeeding sub-paragraph, where the applicant for the grant or renewal of a product licence who is liable to a supplementary fee satisfies the Minister that in the course of a business carried on by him during the relevant year the gross value of sales, calculated at manufacturer's prices, of all medicinal products to which paragraph 2 of Part IV of this Schedule applies was an amount less than £200,000, the supplementary fee payable shall, instead of £200, be a lesser supplementary fee equivalent to 0·1 per cent of that amount of the gross value of sales (reduced to the nearest multiple of £10) or £50 whichever is the greater.

(*b*) Where the applicant as aforesaid is a retail pharmacist and the medicinal product in respect of which the application is made is a retail pharmacist product which is or is to be imported, and the applicant satisfies the Minister that the gross value of sales as aforesaid of all medicinal products manufactured outside the United Kingdom was an amount less than £10,000 then the supplementary fee payable shall, instead of the lesser rate as aforesaid, be a lesser rate equivalent to 0·5 per cent of the amount of the gross value of sales (reduced to the nearest multiple of £5) or £5 whichever is the greater.

3. For the purposes of paragraphs 1 and 2 of this Part of this Schedule, in calculating the gross value of sales of medicinal products there shall be included the gross value of the sales of any substance or article specified in the Medicines (Surgical Materials) Order 1971(**a**), in the Medicines (Control of Substances for Manufacture) Order 1971(**b**) or specified in any order made under sections 104 or 105 of the Act subsequent to the coming into force of these regulations for the time being in force which directs that sections 7, 8, 31 or 32 of the Act shall have effect in relation to medicinal products as those sections have effect in relation to medicinal products within the meaning of the Act.

4. Where an applicant for a licence (hereinafter referred to as a "new licence") is the holder of one or more licences (hereinafter referred to as "existing licences") and each licence is a manufacturer's licence specified in entry No. 4 of Part I of this Schedule and each such licence is in respect of manufacture or of manufacture and assembly in the course of a separate business, the provisions of regulation 8 shall not apply but in assessing the annual fee payable in connection with the application for the new licence only the gross value of sales in the course of each separate business shall be taken into account for the purposes of this Part of this Schedule and that fee shall be reduced by such amount (if any) by which the aggregate of those fees and the fees for the existing licences exceeds £2,500.

(**a**) S.I. 1971/1267 (1971 II, p. 3632). (**b**) S.I. 1971/1200 (1971 II, p. 3506).

5. Where two applications are made for product licences in respect of corresponding fee periods and in respect of each a supplementary fee is payable and—

(*a*) where each such licence is in respect of dealings in the course of a separate business, or

(*b*) where each such licence is a product licence of a different description within the meaning of paragraph 2 of Part IV of this Schedule,

the provisions of regulation 8 shall not apply but in assessing the supplementary fee payable in connection with each application for a licence only the gross value of sales in the course of that separate business or, as the case may be, the gross value of sales of all medicinal products manufactured outside the United Kingdom or of substances or articles to which section 43 of the Act relates, or of medicinal products manufactured otherwise than in accordance with a manufacturer's licence, shall be taken into account for the purposes of this Part of this Schedule and the supplementary fee last payable shall be reduced by such amount (if any) by which the aggregate of those supplementary fees exceeds £200.

6. Where two licences are both manufacturer's licences specified in entry No. 4 of Part I of this Schedule or are both product licences in respect of which a supplementary fee is payable but which are not licences to which paragraphs 3 or 4 of this Part of this Schedule refer, the relevant year for the purposes of assessing the lesser rates of fee in accordance with this Part of this Schedule for the existing licence shall be treated as the relevant year for the purposes of assessing the lesser rate for the new licence.

7. Where the amount of an annual fee or supplementary fee has been reduced under paragraphs 3 and 4 of this Part of this Schedule by virtue of the holder of the licence being the holder of another licence and he ceases to be the holder of that other licence, the amount by which the annual fee, or, as the case may be, the supplementary fee was reduced shall be disregarded and the balance of the annual fee calculated on the basis of the amount by which the annual fee or supplementary fee was reduced shall thereupon become payable.

8. Where figures of the gross value of sales as aforesaid are not available to the applicant because he was not carrying on a business as aforesaid during the relevant year, the provisions of paragraphs 1, 2, 3, 4 or 5 of this Part of this Schedule shall apply with the following modification:—

(*a*) where the applicant for a licence has taken over an existing business or running concern whether by purchase or merger or otherwise, the gross value of sales of that business or concern during the relevant year may be treated as the gross value of sales for the purpose of calculating the lesser rate of fee or supplementary fee as the case may be;

(*b*) in any other case, an estimate of the gross value of sales as aforesaid for the first fee period of the licence in respect of which the application is made may be treated as the gross value of sales for the purpose of calculating the lesser rate of fees or supplementary fee as the case may be.

9. Where the applicant for a licence was carrying on a business as aforesaid during only part of the relevant year, the average of the gross value of sales for a period of twelve months calculated on the basis of the gross value of sales during that part of the relevant year when the applicant was carrying on a business as aforesaid, shall be treated as the gross value of sales for the purpose of calculating the lesser rate of fee or supplementary fee as the case may be.

10. The medicinal products referred to in paragraph 1 of this Part of this Schedule do not include substances or articles specified in paragraph 3 of Part II of this Schedule or medicinal products whose manufacture is exempt from the restrictions imposed by section 8 of the Act by virtue of an exemption conferred by or under sections 9 to 15 of the Act.

11. The medicinal products referred to in paragraph 2 of this Part of this Schedule are those for which product licences are held or for which application has been made by the applicant but do not include medicinal products specified in paragraph 3 of Part II of this Schedule.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations replace the Medicines (Fees) Regulations 1971. The regulations prescribe the fees payable in connection with applications for licences or certificates under the Medicines Act 1968. The regulations provide for the payment of fees by instalments, for the refund of fees in certain circumstances, for the payment of a single annual fee for any number of licences of the same type held by the same person, for certain specified reliefs for businesses with a small turnover, for reduced fees for manufacturer's licences in respect of certain retail suppliers, allow for more flexibility in the calculation of fees charged where there is transfer of responsibility for a product from one person to another and provide, in certain circumstances, for the suspension of licences where sums by way of, or on account of, fees are unpaid, and for the recovery of unpaid fees. The regulations do not increase the rate of fees in the previous regulations, but holders of existing licences will be able to take advantage of any relevant concession provided for in these regulations.

SI 1975/366
ISBN 0-11-050366-X

