STATUTORY INSTRUMENTS

1976 No. 347

MEDICINES

The Medicines (Fees) Regulations 1976

Made - - -	*4th March* 1976
Laid before Parliament	*5th March* 1976
Coming into Operation	*6th March* 1976

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 conferred by 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 1976 and shall come into operation on 6th March 1976.

(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 Schedule 1 means the appropriate amount set out in column 3 of that Part of that Schedule 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 Part I of Schedule 1 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 1946(**d**), the National Health Service Reorganisation Act 1973(**e**), the National Health Service (Scotland) Act 1972(**f**) or the Health and Personal Social Services (Northern Ireland) Order 1972(**g**);

(**a**) 1971 c. 69.
(**b**) 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.
(**d**) 1946 c. 81.
(**e**) 1973 c. 32.
(**f**) 1972 c. 58.
(**g**) S.I. 1972/1265 (N.I. 14).

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

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

"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, and includes the part of 12 calendar months commencing on the date on which these regulations shall come into force and ending on the 31st day of August 1976;

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

"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 Part I of Schedule 1 and in relation to annual fees means that each of such fees is a fee described in the same paragraph of Part I of that Schedule;

"preliminary fee" in relation to any licence described in column 1 of Part I of Schedule 1 means a single sum equal to the annual fee which would be payable if the licence was granted in the licence year in which the application was made, such fee to be payable in accordance with the provisions of regulation 14;

"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;

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

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 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.

(**a**) S.I. 1971/1267 (1971 II, p. 3632).
(**b**) S.I. 1971/1200 (1971 II, p. 3506).
(**c**) S.I. 1975/533 (1975 I, p. 1754).

(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.

Revocation and savings

2.—(1) The Medicines (Fees) Regulations 1975(b) (in these regulations called "the 1975 regulations") are hereby revoked.

(2) Such revocation shall not affect any fee or any part of a fee paid or to be paid under the Medicines (Fees) Regulations 1971(c) (in these regulations called "the 1971 regulations") or under the 1975 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 the 1971 regulations or the 1975 regulations, as the case may be, 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 the 1975 regulations and any fee or part thereof to be paid under the 1971 regulations or the 1975 regulations, as the case may be, shall be treated as due under these regulations.

(3) Such revocation shall not affect any notice given or any suspension made under the 1971 regulations or the 1975 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 or the 1975 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 any application for the grant or renewal of any product licence of a kind described in column 1 of Part I of Schedule 1 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, but not the renewal, of any product licence, there shall be payable by the applicant an initial fee, and, where regulation 8 applies, an inspection fee, in respect of each description of medicinal product to

(a) 1889 c. 63. (b) S.I. 1975/366 (1975 I, p. 1144).
(c) S.I. 1971/1449 (1971 III, p. 4102). (Revoked by the 1975 Regulations).

which the licence is to relate: provided that only one initial 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.

(4) The provisions of paragraph (3) shall not apply so as to impose any liability to pay an initial 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 thereof, if the applicant is already the holder of a product licence in respect of a medicinal product so specified in the same paragraph.

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

Clinical trial and animal test certificates

4. In connection with each application for the issue or renewal of a clinical trial certificate or an animal test certificate described in column 1 of Part I of Schedule 1, an initial fee shall be payable by the applicant.

Manufacturer's licences and wholesale dealer's licences

5.—(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 Part I of Schedule 1, 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, save 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 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) Subject to the following provisions of these regulations, in connection with an application for the grant, but not the renewal, of any manufacturer's or wholesale dealer's licence, there shall be payable by the applicant an initial fee, a preliminary fee and, where regulation 8 applies, an inspection fee.

(3) No initial 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 initial fee payable will be the amount shown in whichever of paragraphs 5(*a*), 5(*b*), 5(*c*) or 6 of column 2 of Part I of Schedule 1 is appropriate in connection with such additional premises.

(4) Subject to paragraphs (5) and (6), there shall be payable in respect of an application for the grant of a manufacturer's licence made on or after the coming into operation of these regulations an additional sum equal to 3 times the amount of the preliminary fee which would have been payable under the 1975 regulations.

(**a**) S.I. 1975/533 (1975 I, p. 1754).

(5) If the Minister, as defined in regulation 10, is satisfied that the applicant, in the course of a business carried on by him, 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, then:—

(i) during the period between 1st September 1972 and 31st August 1973, the additional sum payable in accordance with the provisions of paragraph (4) shall be equivalent to twice the amount of the preliminary fee mentioned therein,

(ii) during the period between 1st September 1972 and 31st August 1974, the additional sum payable in accordance with the provisions of paragraph (4) shall be equivalent to the amount of the preliminary fee mentioned therein,

(iii) during the period between 1st September 1972 and 31st August 1975, no additional sum shall be payable in accordance with the provisions of paragraph (4).

(6) If the Minister is satisfied that such manufacture or assembly during any period referred to in paragraph (5) was exempt from the restrictions imposed by section 8 of the Act by virtue of an exemption granted by sections 9 to 12 of the Act or by an order made under section 15 of the Act, the provisions of paragraph (4) shall apply as if no such manufacture or assembly had taken place during that period.

Fees in respect of variations

6.—(1) In connection with an application for the variation of any product licence, manufacturer's licence or wholesale dealer's licence, fees shall be payable by way of variation fees as provided in the following paragraphs of this regulation and in Part VII of Schedule 1, 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, the pharmaceutical form or the indications for use of the medicinal product, there shall be payable by the applicant a fee of £25.

(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 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) 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 variation fee equal to the amount shown in whichever of paragraphs 5(*a*), 5(*b*) or 5(*c*) or 6 of column 2 of Part I of Schedule 1 is appropriate.

(6) 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 variation fee of £25.

(7) In addition to the fees (if any) payable in accordance with the preceding paragraphs, on an application for the variation of a product licence, annual fees shall become payable as if the application had been an application for the grant of a licence as so varied.

Change of responsibility

7.—(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 initial fee payable in connection with such application shall be £25, 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 initial fees in respect of such assignment shall be equal to 0·25 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 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 £10,000, whichever is the lesser sum, if such sum is less than the fee payable under paragraph (1).

Inspection fees

8.—(1) 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, the sum of £500 or such lesser sum as the Minister may determine shall be payable by way of an inspection fee in addition to any other fees which may be payable under the provisions of these regulations.

(2) If a sum greater than that payable under paragraph (1) 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 paragraph (1) 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.

Fees for export certificates

9.—(1) A fee of £3 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 period of 12 calendar months ending on 31st August in the year preceding the date of the application, paid fees in respect of licences amounting to £500 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 the 1975 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 1971 regulations, or to pay annual fees in respect of a period of 5 years under the provisions of the 1975 regulations, 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

PAYMENTS, INSTALMENTS, REFUNDS AND SUSPENSIONS

Payment of fees to Ministers

10. Any sums which under the provisions of these regulations become payable by way of or on account of any fees 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.

Payments in advance

11.—(1) Any person who is the holder of a product licence and who desires to do so may notify the licensing authority of his intention to apply for a renewal of such licence in due course and may pay in respect of each subsequent licence year in which he does not make an application in relation to a licence of the same kind, the sums which would have been payable by way of annual fees of that kind if he had made an application in the year in which he so notified the licensing authority.

(2) Where any person makes an application in the licence years ending on 31st August 1976, 31st August 1977 or 31st August 1978, not having previously made any application after the coming into operation of these regulations for the grant, renewal or variation of a product licence of the same kind, then, if he was the holder of a licence of that kind in the year preceding the application, the sum payable in respect of his application may be adjusted in accordance with the subsequent provisions of this regulation if he has made an advance payment in accordance with paragraph (1), whether before or after the coming into force of these regulations.

(3) Where any person has paid any sums in respect of all or any of the licence years referred to in paragraph (2) and such sums have not been repaid, then—

(*a*) the sum paid by way of advance payment in respect of the earlier or earliest of the licence years in respect of which the advance payment was made shall be treated as payment towards the preliminary fee payable in respect of the application referred to in paragraph (2) or the annual fee payable in respect of the first licence year subsequent to the grant of a licence upon such application, as the case may be, and any further sums paid by way of advance payment shall be treated as payment on account of fees for subsequent years;

(*b*) where an advance payment in respect of fees has been made in respect of a particular licence year, such payment being a sum calculated in respect of that year in accordance with the provisions of Part VI of Schedule 1, then, if that sum is to be treated as payment towards any subsequent licence year in accordance with sub-paragraph (*a*) above, the percentage of turnover used in calculating the fee payable in respect of such subsequent year shall be that appropriate to the year in respect of which the advance payment was made and not that provided for by the said Part of the said Schedule for such subsequent year.

(4) Any sum paid by any person in accordance with the provisions of 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 paragraph (1) relates, and no liability for an annual fee of the same kind has arisen under the provisions of these regulations.

(5) If, by virtue of the provisions of this regulation, the sum payable by any holder of a licence is greater than the sum which would be payable if those provisions were not taken into account, then those provisions shall not apply and any sum paid under the provisions of paragraph (1) shall be treated as a part payment in advance of the first annual fee payable under the provisions of these regulations.

Time for payment of fees other than annual and preliminary fees

12. All sums payable by way of initial fees, inspection fees, variation fees and fees for export certificates 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.

Time for payment of annual fees

13.—(1) Subject to paragraph (2), 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.

Time for payment of preliminary fees

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

(2) Where at the time of application the applicant produces evidence as to turnover or notifies the Minister that he proposes to produce such evidence in accordance with Part V of Schedule 1, payment may be made by instalments as follows:—

(*a*) a first instalment of the minimum amount in accordance with the appropriate paragraph in column 3 of Part I of Schedule 1;

(*b*) a second instalment, being the balance of the amount due, payable upon the grant of the licence or upon notice by the Minister given in accordance with paragraph (3), whichever first occurs.

(3) Such notice by the Minister as is referred to in paragraph (2) may be served at any time after 120 days from the date of receipt by the licensing authority 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) of the Act 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.

Adjustment of provisional payment

15. Where the annual fee in respect of any licence year has been determined in accordance with the provisions of paragraph 6(*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.

Refund and set off of fees

16.—(1) 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 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 fee in respect of any licence year has been determined in accordance with the provisions of paragraph 6(*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.

(*b*) 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 5(*a*) of Part V of Schedule 1 or paragraphs 1 or 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.

(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 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.

(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 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.

(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.

(7) 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 the sum paid in respect of such preliminary fee is greater than the sum payable by way of the first annual fee in respect of the licence which has been granted, that annual fee shall not be payable, and

(*b*) if that preliminary fee payable is less than or equal to that annual fee, the preliminary fee may be set off against the sum payable by way of annual fee in respect of that application.

Suspension of licences

17. Where, after the grant of any licence described in column 1 of Part I of Schedule 1, 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.

Provisions with regard to initial fees

18. The Minister may waive payment of or reduce any sum otherwise payable by way of initial fees payable in accordance with column 2 of Part I of Schedule 1 or, if such sum has been paid, refund it in whole or in part—

(*a*) in a case where the higher fee of £1,800 is payable in respect of 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 in question during any calendar year does not exceed a sum specified for that purpose by the Minister at the time of the grant of the licence.

PART IV

RECOVERY OF FEES

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 V

TRANSITIONAL PROVISIONS

20.—(1) Where, on the coming into operation of these regulations, the holder of a product licence in respect of medicinal products for either human or veterinary use would be liable to pay—

(*a*) an annual fee of £10 under the 1975 Regulations in respect of that licence and an annual fee of £50 under the provisions of these regulations then, in respect of the licence years ending on 31st August 1976 and 31st August 1977 the minimum amount payable by way of annual fees in respect of each of those licence years shall be £10;

(*b*) supplementary fees in respect of that licence under the 1975 Regulations, then the amount of such fees paid in any licence year shall be set off against any annual fees to which the holder of the licence becomes liable in respect of that same licence year under the provisions of these regulations.

(2) Where, on the coming into operation of these regulations, the holder of a manufacturer's licence is liable to pay annual fees under the provisions of column 3 of paragraphs 4, 5 or 6 of Part I of the Schedule to the 1975 Regulations, such annual fees payable in any licence year may be set off against the fees payable in that licence year in respect of that licence under the provisions of these regulations.

(3) Where a retail pharmacist transfers his retail pharmacy business to another person before 31st August 1977, then the annual fee payable by that person in respect of each of the licence years ending on 31st August 1976 and 31st August 1977 shall be the fee set out in paragraph 6(*c*) of column 3 of Part 1 of the Schedule to the 1975 regulations and no further annual fee shall be payable under these regulations in respect of either of those licence years.

(4) (*a*) Where annual fees are payable under these regulations in respect of the licence year ending on 31st August 1976 in respect of product licences for medicinal products for human use, the amount of the annual fees payable shall not exceed £30,000, provided payment of fees payable is made before 31st March 1976.

(*b*) Where annual fees are payable under these regulations in respect of the licence year ending on 31st August 1976 in respect of product licences for medicinal products for animal use, the amount of the annual fees payable shall not exceed £10,000, provided payment of fees payable is made before 31st March 1976.

(5) Where any sum is paid to which any provision of regulation 11 applies and such sum, whether paid before or after the coming into operation of these regulations is paid before 31st March 1976, such payment shall be regarded as having been made in respect of the licence year ending on 31st August 1976; and where such payments are made between 1st April 1976 and 31st August 1976, such payments shall be regarded as having been made in respect of the licence year ending on 31st August 1977.

(6) Where sums have been paid by any person in the circumstances to which paragraph (1) of regulation 11 relates, paragraph 1 of Part VI of Schedule 1 shall apply as if that person had made an application for a product licence of the same kind in the licence year during which the first payment was made.

Barbara Castle,
Secretary of State for Social Services.

25th February 1976.

John Morris,
Secretary of State for Wales.

25th February 1976.

William Ross,
Secretary of State for Scotland.

26th February 1976.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 26th February 1976.

(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 1st day of March 1976.

(L.S.) *N. Dugdale*,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 1st day of March 1976.

(L.S.) *J. A. Young*,
Permanent Secretary.

We consent.

Donald R. Coleman,
M. Cocks,
Two of the Lords Commissioners of Her Majesty's Treasury.

4th March 1976.

SCHEDULE 1 Regulations 1, 3, 4, 5, 6, 11, 14, 15, 16, 17, 18, 20.

PART I

FEES

Column 1 Kind of licence or certificate	Column 2 Initial Fee	Column 3 Annual Fees
1. Product licence (products for human use)	1. (*a*) £1,800, or (*b*) £60, if the product to which the application relates is a product specified in Part II or satisfies the conditions of Part III of this Schedule. (Subject to the provisions of paragraph 3 of Part VII of this Schedule)	1. £50, or an amount calculated in accordance with Parts IV, V and VI of this Schedule, whichever is the greater, except in relation to an application to which paragraphs 1 or 2 of Part VII of this Schedule applies.
2. Product licence (products for veterinary use)	2. (*a*) £1,800, or (*b*) £60, if the product to which the application relates is a product specified in Part II or satisfies the conditions of Part III of this Schedule. (Subject to the provisions of paragraph 3 of Part VII of this Schedule)	2. £50, or an amount calculated in accordance with Parts IV, V and VI of this Schedule, whichever is the greater, except in relation to an application to which paragraphs 1 or 2 of Part VII of this Schedule applies.
3. Clinical trial certificate	3. £50, except in relation to an application to which paragraph 4 of Part VII of this Schedule applies.	3. Nil.
4. Animal test certificate	4. £50, except in relation to an application to which paragraph 5 of Part VII of this Schedule applies.	4. Nil.
5. Manufacturer's licence	5. (*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. (Subject to the provisions of paragraph 3 of Part VII of this Schedule)	5. The amounts specified in paragraphs 5(*a*), (*b*) and (*c*) of column 2, or an amount calculated in accordance with Parts IV, V and VI of this Schedule, whichever is the greater, except in relation to an application to which paragraphs 1, 2 or 6 of Part VII of this Schedule applies.
6. Wholesale dealer's licence	6. £10 for each separate set of premises in which medicinal products to which the licence relates are or are to be stored.	6. £10 for each separate set of premises in which medicinal products to which the licence relates are or are to be stored.

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 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 homœopathic medicine or similar system which is to be sold or supplied solely for use as a homœopathic 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.

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 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 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 preparation, 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 preparation and that the existing preparation has been effectively on the market in the United Kingdom for a period of 5 years ending on the date of the application.

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

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, so however 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—

(*a*) either an initial 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, or

(*b*) the purposes for which the use of the existing preparation may be recommended do not differ substantially from those of the product in respect of which the application is made and the licensing authority is 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.

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 1 or 2 as the case may be

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. Upon payment of an annual fee of a particular kind in respect of a particular licence year calculated in accordance with paragraph 1 of Part VI of this Schedule, no further fee of that kind shall be payable in respect of the same application, notwithstanding that the sum paid falls short of the amount payable under paragraph 2 or 3 as the case may be of Part VI of this Schedule.

4. 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.

5. Where applications for licences of the same kind are made in two successive licence years, then in the second of those years no annual fee shall be payable in respect of the application made in the first of those years, provided that the annual fee payable in respect of the second application has been duly paid.

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

7. Where, as a result of applications being made in different years, two or more annual fees of the same kind become payable in the same licence year, the amount payable shall not exceed the sum calculated in accordance with the higher rate provided for in Table 1, 2 or 3 of paragraph 1 of Part VI of this Schedule in relation to the years in which applications were made.

8. If, after making any adjustments due to be made in accordance with the provisions of paragraphs 5 and 6 of this Part, the total amount payable by way of annual fees of the same kind in the same licence year exceeds the sum calculated in accordance with paragraph 7 of this Part, that total amount shall be abated accordingly, commencing with fees in respect of the applications made earliest in time.

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 include any 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 paragraphs 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 required to be licensed solely by reason that sub-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 manufacturer's 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 include any product the manufacture or assembly of which is subject to any licence held by the applicant or in respect of which he has made an application, 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.

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, then, 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, then, 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.—(*a*) For the purpose of satisfying the Minister for the purposes of paragraph 1 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.

6. 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

(**a**) S.I. 1971/1410 (1971 II, p. 3945).
(**b**) S.I. 1973/2079 (1973 III, p. 7182).

application is made, the provisions of paragraphs 1, 2, 3 and 4 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 for the purpose of making a provisional payment subject to adjustment in accordance with the provisions of regulations 15 or 16(2)(*a*), but not for the purpose of calculating the aggregate of the annual fees in accordance with paragraph 3 of Part VI of this Schedule.

PART VI

CALCULATION OF ANNUAL FEES

1. Where in a licence year shown at the head of a column of the Tables 1, 2 or 3 set out below which relates to the kind of licence in respect of which an application is made, the licence holder submits evidence of turnover in relation to the calendar year which ends 20 months before the end of a licence year (hereinafter referred to as "the relevant calendar year") to the satisfaction of the Minister, the annual fee payable in respect of that licence year shall be such percentage of the turnover as is shown in that column opposite the licence year in which the application is made, except that in relation to the licence years ending on 31st August 1976 and 31st August 1977 the first £200,000 of such turnover shall be disregarded.

TABLE 1

PRODUCT LICENCES FOR MEDICINAL PRODUCTS FOR HUMAN USE

Where application is made in the licence year ending on 31st August of the year:	Rate of annual fee for licence year ending 31st August of the year:				
	1976	1977	1978	1979	1980 or later
1976	0·25%	0·5%	0·5%	0·5%	0·5%
1977	—	0·25%	0·5%	0·5%	0·5%
1978	—	—	0·25%	0·5%	0·5%
1979	—	—	—	0·25%	0·5%
1980 or later	—	—	—	—	0·5%

TABLE 2

PRODUCT LICENCES FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Where application is made in the licence year ending on 31st August of the year:	Rate of annual fee for licence year ending on 31st August of the year:				
	1976	1977	1978	1979	1980 or later
1976	0·25%	0·5%	0·5%	0·5%	0·5%
1977	—	0·25%	0·5%	0·5%	0·5%
1978	—	—	0·25%	0·5%	0·5%
1979	—	—	—	0·25%	0·5%
1980 or later	—	—	—	—	0·5%

TABLE 3

MANUFACTURER'S LICENCES

Where application is made in the licence year ending on 31st August of the year:	Rate of annual fee for licence year ending on 31st August of the year:			
	1976 or 1977	1978	1979	1980 or later
1976	0·025%	0·05%	0·05%	0·05%
1977	0·025%	0·05%	0·05%	0·05%
1978	—	0·025%	0·05%	0·05%
1979	—	—	0·025%	0·05%
1980 or later	—	—	—	0·025%

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 £2,000 in respect of each set of premises at which manufacturing or assembly is carried on by the licence holder.

3. 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—

(i) where the licence is a product licence for a medicinal product for human use, a sum which is 3·0 per cent. of that turnover multiplied by the number of years for which the licence was in force, or

(ii) where the licence is a product licence for a medicinal product for animal use, a sum which is 3·0 per cent. of that turnover multiplied as aforesaid, or

(iii) where the licence is a manufacturer's licence, a sum which is 0·3 per cent. of that turnover multipled as aforesaid.

PART VII

LESSER AMOUNTS OF FEES

1. Where an applicant for the grant, renewal or variation of a licence as described in paragraphs 1, 2 or 5 of column 1 of Part I of this Schedule, or the holder of such a licence satisfies the Minister that, in the course of a business carried on by him during the calendar year which ends 20 months before the end of a licence year in respect of which annual fees are payable, the gross value of goods, whether medicinal products or other products, sold or supplied or services rendered (the value of goods supplied or services rendered being taken to be the consideration received in respect thereof) was less than £10,000, the total amount payable by way of annual fees for that licence year shall, instead of the amount which would otherwise be payable under the provisions of this Schedule, be 0·5 per cent. of that gross value, rounded up to the nearest £10.

2. Where the holder of a product licence or a manufacturer's licence or of both such licences whose licenseable activities relate solely to products sold or supplied by retail or in circumstances amounting to retail sale from the premises where they are manufactured or assembled, the products not being advertised, satisfies the Minister that his turnover calculated in accordance with Part V of this Schedule in respect of such medicinal products sold or supplied in the calendar year which ends 20 months before the end of the licence year in respect of which annual fees are payable was an amount less than £10,000, the total amount payable by way of annual fees shall, instead of the amount otherwise payable under this Schedule, be 0·5 per cent. of that turnover, rounded up to the nearest £10.

3. Where the circumstances described in paragraphs 1 and 2 of this Part of this Schedule apply, any initial fees or variation fees payable shall be reduced so that the total amount paid by way of such fees in any one licence year shall not exceed £50.

4. Where an application is made for a clinical trial certificate by a doctor or dentist by whom under or 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 initial fee payable shall be £1.

5. 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 (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 are satisfied, the initial fee payable shall be £1.

6. 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(**c**), as amended(**d**), 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

(**a**) S.I. 1972/1200 (1972 II, p. 3553).
(**b**) S.I. 1974/498 (1974 I, p.1768).
(**c**) S.I. 1971/1450 (1971 III, p. 4118).
(**d**) S.I. 1972/1200 (1972 II, p. 3553).

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 judgment as to the treatment required,

then the annual fee payable shall, instead of the amount otherwise payable under the provisions of this Schedule, be the total of the amounts shown in paragraphs 5(*b*) and 6(*c*) of column 3 of Part I of the Schedule to the 1975 regulations in respect of the licence years ending on 31st August 1976 and 31st August 1977 and in respect of each subsequent licence year the amount payable shall be £50 for each of the premises at which such activities are conducted.

SCHEDULE 2 Regulation 3(3)

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. Homœopathic 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.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations replace the Medicines (Fees) Regulations 1975. The Regulations prescribe the fees payable in connection with applications for licences or certificates under the Medicines Act 1968. The Regulations provide for annual fees to be calculated on the basis of a percentage of annual turnover, providing certain provisions in respect of small businesses and for the manufacture of medicinal products unlikely to be of commercial value or likely to be manufactured only in small quantities. Liability for supplementary fees will no longer arise, but inspection fees have been introduced to cover cases where a visit to an applicant's premises, other than a routine inspection, becomes necessary and fees are introduced in respect of export certificates in certain cases. The maximum amounts payable by way of fees for the whole period during which any licence is in force can be calculated. There are concessions for persons who choose to pay fees in advance and provisions for payment of fees by instalments, for refunds and set-offs. There continue to be provisions, 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. These Regulations also contain transitional provisions.

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