1971 No. 1449

MEDICINES

The Medicines (Fees) Regulations 1971

Made - - -	31*st August* 1971
Laid before Parliament	2*nd September* 1971
Coming into Operation	1*st September* 1971

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 Health and Social Services for Northern Ireland, the Minister of Agriculture, Fisheries and Food and the Minister of Agriculture for Northern Ireland, acting jointly, with the consent of the Treasury in exercise of their powers under subsections (1) and (2) of section 1 of the Medicines Act 1971(a) 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 1971 and shall come into operation on 1st September 1971.

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

"the Act" means the Medicines Act 1968(b);

"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 Schedule 1 to these regulations means an application made under and in accordance with regulations made under section 18 or 36 of the Act which are for the time being in force;

"The Committee on Safety of Drugs" means the committee appointed in June 1963 by the Ministers concerned with health in England and Wales, in Scotland and in Northern Ireland respectively to advise on the safety, quality and efficacy of medicinal products and to promote the collection of reports of adverse reactions and to assess their significance;

"medicinal product" includes articles or substances specified in orders made under section 104 or 105 of the Act which are for the time being in force and which direct that Part II of the Act shall have effect in relation to such articles or substances as that Part has 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;

(a) 1971 c. 69. (b) 1968 c. 67.

"retail pharmacist product" means any medicinal product, substance or article 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;

"The Veterinary Products Safety Precautions Scheme" means the scheme drawn up in 1964 following discussions between the Minister of Agriculture, Fisheries and Food, the Minister of Health, the Secretary of State concerned with agriculture and with health in Scotland, and representatives of professional and commercial organisations for the purpose of safeguarding human beings and animals against risks arising from the use of veterinary products;

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

(3) Except in so far as the context otherwise requires, any reference in these regulations to any enactment or order or regulations shall be construed as a reference to that enactment or order or those regulations as the case may be as amended, extended or re-enacted by any other enactment, order or regulations.

(4) The Interpretation Act 1889(a) applies for the purpose of the interpretation of these regulations as it applies for the purpose of the interpretation of an Act of Parliament.

PART II

FEES

Initial Fee and Duration Fee

2. For the purposes of this Part and Parts III and IV of these regulations—

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

"duration fee", in relation to any licence described in that first column, means the total amount calculated on the basis of the rate specified in the third column of that Part in relation to that licence multiplied by a number of years consisting of the calendar year in which the licence commences plus the number of subsequent calendar years (if any) during the whole of which the licence is to remain in force;

"rate", in relation to any duration fee, includes such rate specified in the third column of Part I of Schedule 1 to these regulations as adjusted under the provisions of Parts IV and V or, as the case may be, Part IV of Schedule 1.

Product licences

3.—(1) Subject to the following provisions of these regulations, in connection with each application in pursuance of the Act for the grant or renewal of any product licence there shall be payable by the applicant an initial fee and a duration fee.

(2) 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 renewal of any product licence, or the grant of a product licence—

(a) 1889 c. 63.

(*a*) to which a person is entitled by virtue of that person's entitlement to the grant of a licence of right ; or

(*b*) in respect of a medicinal product, substance or article for which the agreement to marketing of the Committee on Safety of Drugs had been sought or a submission for clearance under the Veterinary Products Safety Precautions Scheme had been made before 1st July 1971 and either—

(i) where the agreement or clearance as aforesaid has been notified between 1st September 1970 and 31st August 1971, the application for the product licence in respect of that medicinal product, substance or article is made within a period of 12 months from the date of such notification or the date appointed by an order under section 25(1) of the Act (closing date for applications for licence of right) whichever is the earlier, or

(ii) where the agreement or clearance as aforesaid has not been notified before 1st September 1971, the application for the product licence in respect of that medicinal product, substance or article is made before the date appointed as aforesaid, or

(*c*) in respect of any medicinal product, substance or article specified in any paragraph of Part II of Schedule 1 to these regulations if the applicant is already the holder of a product licence in respect of a medicinal product, substance or article so specified in the same paragraph ; or

(*d*) in respect of a medicinal product, substance or article for which a licence issued to the applicant under Part II of the Diseases of Animals Act 1950(**a**) or the Diseases of Animals Act (Northern Ireland) 1958(**b**) is or was in force on 1st September 1971, or, where such licence has not been issued, an application for such licence in respect of that medicinal product, substance or article is made before such date.

(3) For the purposes of these regulations any application for the variation of a product licence shall be treated as an application for the grant of a product licence if the medicinal product, substance or article to which the product licence as varied is to relate, on the one hand and the medicinal product, substance or article to which the product licence to be varied relates, on the other hand, are medicinal products, substances or articles which could not have been included in the same application for the purposes of the grant of a product licence or, if so included, a higher initial fee would have been payable in respect of the application for the product licence to be varied.

Clinical trial and animal test certificates

4.—(1) Subject to paragraph (2) of this regulation, in connection with each application in pursuance of the Act for the issue of a clinical trial certificate or an animal test certificate there shall be payable by the applicant an initial fee.

(2) The provisions of paragraph (1) of this regulation shall not apply to a clinical trial certificate or an animal test certificate—

(*a*) to which a person is entitled by virtue of the provisions of section 37(4) of the Act ; or

(**a**) 1950 c. 36. (**b**) 1958 c. 13 (N.I.).

(*b*) in respect of a clinical trial or medicinal test on animals as the case may be for which the agreement of the Committee on Safety of Drugs had been sought or a submission for clearance under the Veterinary Products Safety Precautions Scheme had been made before 1st July 1971 and either—

(i) where the agreement or clearance as aforesaid has been notified between 1st September 1970 and 31st August 1971, the application for such certificate in respect of that trial or test is made within a period of 12 months from the date of such notification or the date appointed by an order under section 37(4) of the Act whichever is the earlier; or

(ii) where the agreement or clearance as aforesaid has not been notified before 1st September 1971 the application for such certificate in respect of that trial or test is made before the date appointed as aforesaid.

Manufacturer's licence and wholesale dealer's licence

5.—(1) Subject to the following provisions of these regulations, in connection with each application in pursuance of the Act for the grant or renewal of any manufacturer's licence or wholesale dealer's licence described in the first column of Part I of Schedule 1 to these regulations there shall be payable by the applicant a duration fee.

(2) For the purposes of these regulations any application for the variation of a manufacturer's licence or a wholesale dealer's licence by virtue of which variation a different rate of duration fee would be payable, shall be treated as an application for the grant of a licence and—

(*a*) the licence in respect of which the application for variation has been made shall be treated as revoked as from the date of variation, and

(*b*) the unexpired period of the duration of that licence as from the date of such variation shall be treated as the duration of the licence for the purposes of calculating the duration fee.

Variation Fees

6.—(1) Except as provided in regulations 3(3) and 5(2) of these regulations, in connection with an application in pursuance of the Act for the variation of any product licence, manufacturer's licence or wholesale dealer's licence described in the first column of Part I of Schedule 1 of these regulations 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) For the purpose of these regulations where an application for the grant of a product licence or a manufacturer's licence is in respect of dealings, manufacture or assembly of medicinal products, substances or articles in respect of which a product licence or a manufacturer's licence, as the case may be, has been granted to a person other than the applicant and the rights to such dealings or, as the case may be, manufacture or assembly have been assigned to the applicant, that application may be treated as an application for a variation as aforesaid provided the duration of the licence applied for is not to exceed the unexpired period of the duration of the licence granted to that other person.

PART III

PAYMENTS INSTALMENTS REFUNDS AND SUSPENSIONS

Payment of fees to Ministers

7. 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 (hereinafter in these regulations referred to as "the Minister").

Time for payment of fees

8. Except as provided in the other provisions of this Part of these regulations all sums payable by way of fees under the provisions of these regulations shall become due for payment at the time of the application for the grant, issue, renewal or variation of any licence or certificate as the case may be or, where such application is made before these regulations come into operation, on the day these regulations come into operation.

Payment by instalments

9.—(1) An applicant for the grant of a product licence in respect of which the higher initial fee is payable, may pay that 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 before the licence is granted.

(2) Except as provided in the following paragraph of this regulation, an applicant for the grant or, as the case may be, renewal of any licence described in the first column of Part I of Schedule 1 to these regulations may pay the duration fee payable in two instalments as follows :—

(i) a first instalment of a sum equivalent to half the rate of the duration fee for that licence payable at the time of making the application, and

(ii) a second instalment of the balance of the duration fee payable before that licence is granted.

(3) An applicant who, in accordance with the provisions of the preceding paragraph, has paid a first instalment may, with the consent of the Minister, pay the balance of the duration fee payable by instalments as follows :—

(i) a second instalment of a sum equivalent to the first instalment before the licence is granted, and

(ii) thereafter annually on each anniversary of the date on which the licence commences to operate, a sum equivalent to the rate of the duration fee for that licence until the balance of the duration fee payable has been paid.

(4) The consent of the Minister for the purposes of the preceding paragraph shall be sought by giving notice in writing to the Minister at the time of making the application of the applicant's wish to pay by means of instalments as specified in paragraph (3) of this regulation.

(5) For the purposes of paragraph (3) of this regulation, the date on which a licence commences in the case of any licence granted by virtue of the applicant's entitlement to a licence of right shall be the day appointed under section 17 of the Act or, if there are two or more such days appointed, the day appointed relevant to the licence in respect of which the duration fee is

payable, unless in his application the applicant has requested that the licence should commence at an earlier date and a licence has been granted accordingly, in which case that earlier date shall be treated as the date on which that licence commences.

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

(7) Subsections (5) and (6) of Section 27 of the Act (which among other things provides, in connection with an application for a licence of right, that the Act shall have effect in certain circumstances as if the licence had been granted) shall not apply in relation to an application for a licence to which a person is entitled by virtue of that person's entitlement to the grant of a licence of right, while there remains unpaid any sum due by way of or on account of fees payable in accordance with the provisions of these regulations in respect of that application.

Payment of subsequent liability to product licence surcharge

10.—(1) Where a surcharge to the rate of duration fee in respect of a product licence becomes payable after the application but before the grant or renewal of the licence the total amount of surcharge calculated on the same basis as the duration fee shall thereupon become payable and for the purposes of payment by instalments under the provisions of this Part of these regulations that amount together with the duration fee payable at the time of the application shall be treated as the duration fee payable in respect of that application.

(2) Where a surcharge as aforesaid becomes payable after the grant or renewal of the licence the total amount of surcharge (calculated on the basis of the appropriate rate of surcharge multiplied by the number of years consisting of the year in which the surcharge becomes payable plus the number of subsequent calendar years, if any, during the whole of which the licence is thereafter to remain in force) shall thereupon become payable unless the applicant is already paying instalments of fees in respect of that licence in which case the applicant may thereupon pay only a sum equivalent to the appropriate rate of surcharge and thereafter add to those instalments a sum equivalent to that rate of surcharge.

Payment of estimate adjustment

11.—(1) Subject to the provisions of paragraph (2) of this regulation, where the rate of the duration fee has been assessed on the basis of an estimate of the gross value of sales under the provisions of paragraph 3(*b*) of Part V of Schedule 1 to these regulations 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 duration fee payable calculated on that basis on the one hand and the duration fee calculated on the basis of the figure of the actual gross value of sales on the other shall thereupon become payable.

(2) Any sum that becomes payable under the provisions of the preceding paragraph may be added to the duration fee payable on the application for the renewal of the licence in respect of which an estimate as aforesaid had been made and both sums may together be treated as the duration fee payable in connection with that application, and the proportion of that total in relation to the number of years of the duration of the renewal of that licence may be treated as the rate of the duration fee for that licence for the purpose of payment of fees by instalments under the provisions of these regulations.

Refund and set-off of fees

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

(2) Where after payment of the whole or any instalment of any duration 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 was fixed by the grant or renewal, the Minister may refund to the applicant the whole or any part of a sum equivalent to the difference (if any) between such duration fee as has been paid and the amount of duration fee calculated on the basis of the duration of the licence being the actual duration up to the date of such revocation or expiry.

(3) In addition to the refunds (if any) payable under the provisions of the preceding paragraph, where the date of revocation or expiry as aforesaid is not the date of the anniversary on which the licence commences and does not fall within a period of three months after any such anniversary and provided that at the time of such revocation or expiry the applicant is not the holder of any other licence nor becomes the holder of any other licence during any part of the calendar year in which the licence was revoked or expired, the Minister may refund to the applicant a sum equivalent to three-quarters, one half or one quarter, as the case may be, of the rate of duration fee in respect of that licence if the date of the revocation or expiry was more than three months, six months or nine months respectively after the date of the last such anniversary.

(4) Where after the payment of the whole or any instalment of any duration fee in respect of a product licence and where that fee includes a surcharge, a relevant change of circumstances takes place by virtue of which no surcharge thereafter would have been payable had these circumstances prevailed at the time of the application or subsequently, the Minister may at the end of the duration of that licence refund to the applicant the whole or any part of that proportion of the fees paid as is equivalent to the surcharge the applicant would not have been liable to pay.

(5) Any sums payable to an applicant by way of a 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 may be liable to pay (whether by instalments or otherwise) under the provisions of these regulations.

Suspension of licences

13. Where after the grant of any licence described in the first column of Part I of Schedule 1 to these regulations, any sum due by way of or on account of any fee payable in accordance with the provisions of these regulations remain 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 from the service of such notice the said sum remains unpaid, the licensing authority may forthwith suspend the licence until such sum has been paid.

PART IV

DURATION FEE FOR APPLICANTS WHO ARE HOLDERS OF OR APPLICANTS FOR LICENCES

Modification of Parts II *and* III

14.—(1) The provisions of Parts II and III of these regulations as to dura-

tion fees and the payment (including payment by instalments) and refund of such fees, in relation to applications specified in paragraph (2) of this regulation shall be modified in the manner and to the extent set out in Schedule 2 to these regulations.

(2) The applications to which the preceding paragraph relates, are applications for the grant or renewal of any one of the following kinds of licences, namely, product licence, manufacturer's licence or wholesale dealer's licence of any of the descriptions specified in the first column of Part I of Schedule 1 to these regulations where at the time of the application the applicant is the holder of, or already an applicant for a licence of like kind but not necessarily of the same description as that for which the application or, as the case may be, the other application is made, provided all the licences concerned are to expire during the same calendar year, or during a period of two consecutive calendar years where the earlier licence was or is to be granted in 1971.

PART V

RECOVERY OF FEES

Civil proceedings to recover unpaid fees

15. 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.

Signed by authority of the Secretary of State for Social Services.

Paul Dean,
Parliamentary Under Secretary of State,
Department of Health and Social Security.

12th August 1971.

Signed by authority of the Secretary of State for Wales.

David Gibson-Watt,
Minister of State,
Welsh Office.

27th August 1971.

Gordon Campbell,
Secretary of State for Scotland.

25th August 1971.

W. K. Fitzsimmons,
Minister of Health and Social Services
for Northern Ireland.

16th August 1971.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 24th August 1971.

(L.S.)

J. M. L. Prior,
Minister of Agriculture, Fisheries and Food.

H. W. West,
Minister of Agriculture for Northern Ireland.

17th August 1971.

We consent.

V. H. Goodhew,
Bernard Weatherill,
Two of the Lords Commissioners of
Her Majesty's Treasury.

31st August 1971.

SCHEDULE 1

Regulations 2, 3, 4, 5 and 6.

Part I

Fees

Description of licence or certificate	Initial Fee	Rate of Duration Fee
1. *Product licence*	1. (*a*) £300 or, (*b*) £10, if the medicinal product substance or article to which the application relates is a product, substance or article 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, plus a surcharge, if the conditions specified in Part IV of this Schedule are satisfied, of £200 or such lesser amount as may be appropriate under Part V of this Schedule.
2. *Clinical trial certificate* ...	2. £25	2. Nil.
3. *Animal test certificate* ...	3. £25	3. Nil.
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' 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) applies.	5. Nil.	5. £50
6. *Manufacturer's licence* in respect of the assembly only of any medicinal product substance or article	6. Nil.	6. (*a*) £50 or, (*b*) £10 in the case of a retail pharmacist product.
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

(a) S.I. 1971/1450 (1971 III, p.4118).

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 circumstance to which paragraph (1) 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 treated as 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 orders made under section 104 or 105 of the Act which are for the time being in force and which direct that Part II of the Act shall have effect in relation to such substance or article as that Part has effect in relation to a medicinal product within the meaning of the Act.

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 a product licence in respect of the existing preparations, or was entitled to be the holder of such a product licence by virtue of the applicant's entitlement to a licence of right, 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 these regulations, or if such fee was payable it was the higher initial fee, or

(*b*) that rights under the Patents Act 1949(a) 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 or veterinary practitioners or are available for supply only to the order of a medical or veterinary practitioner, that the medicinal product in

(a) 1949 c. 87.

respect of which the application is made is also only to be supplied or only to be available for supply as aforesaid.

3. The conditions to which paragraph 1 of this Part of this Schedule refers in relations 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 SURCHARGE TO RATE OF DURATION FEE

1. That the applicant is neither the holder of a manufacturer's licence specified in entry No. 4 of Part 1 of this Schedule nor entitled to such a licence by virtue of his entitlement to a licence of right; and

2. that the application is in respect of a product licence of one of the two 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.

PART V

LESSER AMOUNTS OF DURATION FEE AND SURCHARGE

1.—(*a*) Subject to the provisions of the succeeding sub-paragraph, 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 period is hereinafter referred to as the "relevant year") the gross value of sales calculated at manufacturer's prices, of all medicinal products, substances or articles manufactured by him in the United Kingdom was an amount less than £2,500,000, the rate of the duration 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.

(*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 duration fee payable shall, instead of the lesser rate as aforesaid, be a lesser rate equivalent to 0·5 per cent of that amount of the gross value of sales (reduced to the nearest multiple of £5) 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 surcharge satisfies the Minister that in the course of a business carried on by him during the relevant year the gross value of sale calculated at manufacturer's prices, of all medicinal products manufactured outside the United Kingdom, and, except in the case of a retail pharmacist product, of substances or articles to which Section 43 of the Act relates was an amount less than £200,000, the surcharge rate payable shall, instead of £200, be a lesser surcharge 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.

(*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 surcharge rate payable shall, instead of the lesser rate as aforesaid, be a lesser rate equivalent to 0·5 per cent of that amount of the gross value of sales (reduced to the nearest multiple of £5) or £5 whichever is the greater.

3. Where figures as to 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 paragraph 1 and 2 of this Part of this Schedule shall apply with the following modification:—

(*a*) where the applicant 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 surcharge as the case may be;

(*b*) in any other case, an estimate of the gross value of sales as aforesaid for the first year of the duration 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 fee or surcharge as the case may be.

4. Where the applicant 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 surcharge as the case may be.

5. For the purpose of this Part of this Schedule any application for a licence made on or before 31st December 1971 shall be treated as having been made in 1972.

6. The medicinal products referred to in paragraph 1(*a*) of this Part of this Schedule are those medicinal products whose manufacture does not come within the exemptions conferred by or under Part II of the Act, and the substances and articles so referred to are those substances and articles not being medicinal products which by virtue of section 42 of the Act are treated as if they were medicinal products.

Regulation 14. SCHEDULE 2

DURATION FEE FOR APPLICANTS WHO ARE HOLDERS OF OR APPLICANTS FOR LICENCES

Suspension of liability for new licence

1. Except as provided in paragraphs 8 and 9 of this Schedule where and so long as an applicant for the grant of any one of the following kinds of licences, namely, product licence, manufacturer's licence or wholesale dealer's licence of any of the descriptions specified in the first column of Part I of Schedule 1 to these regulations (hereinafter in this Schedule referred to as "new licence") is the holder of a licence of like kind as the new licence but which is not necessarily of the same description (hereinafter in this Schedule referred to as "existing licence") in respect of which a duration fee is payable at a rate equivalent to or in excess of the rate applicable to the new licence, no duration fee shall be payable in connection with the application for the new licence, and any such fee as may have been paid at the time of the application may be refunded

to the applicant subject however to any set-off in accordance with regulation 12(5) of these regulations.

Revival of liability for new licence

2. Where an applicant for a new licence as aforesaid ceases to be the holder of any existing licence as aforesaid, in connection with the application for the new licence a duration fee calculated in the manner specified in paragraph 3 of this Schedule shall thereupon become payable.

Duration fee on revival of liability for new licence

3. The manner of the calculation of the duration fee referred to in the preceding paragraph is that the amount by which the appropriate rate of duration fee is multiplied is the number of years during which or any part of which the new licence as aforesaid is to remain in force as from the date upon which the applicant ceased to be the holder of the existing licence as aforesaid.

Instalments

4.—(1) Where a duration fee (calculated in accordance with paragraph 3 of this Schedule) in respect of a new licence as aforesaid becomes payable upon the applicant ceasing to be the holder of an existing licence as aforesaid the applicant may, with the consent of the Minister, pay that duration fee by instalments as follows:-

(i) a first instalment of a sum equivalent to the rate of the duration fee applicable to the new licence payable on the day the applicant ceases to be the holder of that existing licence, and

(ii) thereafter annually on the anniversary of that day instalments of a sum equivalent to that rate (subject to the last such instalment being of a lesser amount in appropriate cases) until the balance of that duration fee payable has been paid.

(2) Where the applicant for a new licence is the holder of an existing licence in respect of which a duration fee is payable at a rate less than the rate applicable to the new licence, the applicant may, with the consent of the Minister, pay the duration fee payable in respect of the new licence by instalments as follows:—

(i) the first instalment payable before the grant of the new licence of a sum equivalent to the rate of duration fee applicable to the new licence, and

(ii) thereafter annually on the anniversary of the commencement of the new licence, instalments of a sum equivalent to that rate until the balance of the duration fee is paid.

Suspension and revival of liability for existing licence

5. Except as provided in paragraphs 8 and 9 of this Schedule where the applicant for a new licence is the holder of an existing licence in respect of which a duration fee is payable at a rate less than the rate applicable to the new licence, the applicant shall be treated as ceasing to be the holder of that existing licence upon the grant of that new licence and shall continue to be so treated so long as the applicant is the holder of that new licence and in the event of that new licence ceasing to have effect during the period of the duration of that existing licence the provisions of paragraphs 1 to 4 of this Schedule shall apply as if the holder of that existing licence and the date upon which that new licence ceased to have effect were respectively an applicant for a new licence and the date upon which the applicant ceases to be the holder of any existing licence within the meaning of those paragraphs.

Calculation of lesser amount of duration fee for certain new licences which are product and manufacturer's licences

6. Where the new licence and the existing licence are both either manufacturer's licences or specified in entry No. 4 of Part 1 of Schedule 1 to these regulations or are both product licences in respect of which a surcharge is payable but which are not licences to which paragraphs 8 or 9 of this Schedule refer, the relevant year for the purposes of assessing the lesser rates of fee in accordance with Part V of the said Schedule 1 for the existing licence shall be treated as the relevant year for the purpose of assessing the lesser rate for the new licence.

Refund and set-off

7. The provisions of regulation 12 of these regulations (refund and set-off) shall apply to a case where the applicant is under the preceding paragraph treated as ceasing to be the holder of an existing licence as if that licence had been revoked or had expired.

Duration fee for certain manufacturer's licences

8. Where the new licence and the existing licence are both manufacturers' licences specified in entry No. 4 of Part I of Schedule 1 to these regulations and where the new licence is in respect of manufacture or manufacture and assembly in the course of a separate business from that with which the existing licence is concerned, the provisions of the preceding paragraphs of this Schedule shall not apply but in assessing the rate of the duration fee payable in connection with the application for the new licence only the gross value of sales in the course of that separate business shall be taken into account for the purposes of Part V of the said Schedule I and that rate shall be reduced by such amount (if any) by which the aggregate of that rate and the rate for the existing licence exceeds £2,500.

Duration fee for certain product licences

9. Where the new licence and the existing licence are both product licences in respect of each of which a surcharge is payable and—

(*a*) Where the new licence is in respect of dealings in the course of a separate business from that with which the existing licence is concerned, or

(*b*) Where the existing licence and the new licence are product licences of different descriptions within the meaning of paragraph 2 of Part IV of Schedule I to these regulations.

the provisions of the preceding paragraphs of this Schedule shall not apply but in assessing the rate of surcharge payable in connection with the application for the new 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, shall be taken into account for the purposes of Part V of the said Schedule I and that rate shall be reduced by such amount (if any) by which the aggregate of that rate and the rate for the existing licence exceeds £200.

Duration fee when existing licence ceases to be in force

10. In any case to which paragraphs 8 or 9 of this Schedule applies, where the applicant for the new licence ceases to be the holder of an existing licence, in connection with that application for the new licence, the amount by which the rate of duration fee or as the case may be the surcharge was reduced shall be disregarded and the balance of the duration fee, calculated on the basis of the amount by which the rate or surcharge was reduced multiplied by a number of years consisting of the calendar year in which the applicant ceased to be the holder of the existing licence plus the number of subsequent calendar years (if any) during the whole of which the licence is yet to remain in force, shall thereupon become payable but may be paid by appropriate adjustment to any instalments that may be payable in respect of the new licence.

Suspension of new licence

11. Where an applicant for a new licence ceases to be the holder of an existing licence by reason of a suspension under the provision of regulation 13 of these regulations the licensing authority may forthwith suspend any new licence of which the applicant may be a holder and in respect of which any fees are unpaid until the sums by way of fees in respect of the existing licence have been paid.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These 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 and for the suspension of licences when sums by way of, or on account of, fees are unpaid, and for the recovery of unpaid fees.