STATUTORY INSTRUMENTS

1976 No. 1145

MEDICINES

The Medicines (Fees) Amendment Regulations 1976

Made - - - -	21*st July* 1976
Laid before Parliament	26*th July* 1976
Coming into Operation	1*st September* 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:—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Fees) Amendment Regulations 1976 and shall come into operation on 1st September 1976.

(2) These regulations shall be read as one with the Medicines (Fees) Regulations 1976**(c)** (hereinafter referrred to as "the principal regulations").

Amendment to regulation 1 *of the principal regulations*

2. In regulation 1(2) of the principal regulations, in the definition of "medicinal product", after the words "section 105" there shall be inserted "(1)(*a*)".

Amendment to regulation 3 *of the principal regulations*

3. In regulation 3(3) of the principal regulations after the words "an initial fee" there shall be inserted the words "a preliminary fee".

Addition to the principal regulations

4. The principal regulations shall be amended by the addition of the following regulation after regulation 3 thereof:—

"*Renewal of product licences which are licences of right*

3A.—(1) In connection with any application for the renewal of a product licence which is a licence of right, except any such application as is made in the

(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) S.I. 1976/347 (1976 I, p. 968).

manner mentioned in paragraph (2)(*a*) or (*b*) of this regulation, there shall be payable by the applicant, in addition to any other fee payable by virtue of any other provision of these regulations, a renewal fee of £60 in respect of each description of medicinal product to which such application relates.

(2) Where an application is made—

(*a*) for the first renewal of a product licence for a medicinal product for human use or animal use which is a licence of right on such form as may from time to time be approved by the licensing authority under regulation 2(2) of the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974**(a)**, (in this regulation referred to as "the Renewal Applications Regulations") in respect of the renewal of such product licence for medicinal products for human use or animal use respectively for a period of less than 5 years, or

(*b*) for the renewal for a further period of a product licence which is a licence of right which has been renewed on an application to which sub-paragraph (*a*) of this paragraph applies on such form as may from time to time be approved by the licensing authority under regulation 2(2) of the Renewal Applications Regulations in respect of the further renewal of such product licence for medicinal products for human use or animal use respectively which have been renewed,

the renewal fee of £60 mentioned in paragraph (1) of this regulation shall not be payable in respect of such an application, but there shall be payable by the applicant a renewal fee of £25 in respect of each application in respect of medicinal products for human use or animal use respectively, without regard to the number of descriptions of medicinal products to which each application relates and where an applicant makes more than one application in respect of medicinal products for human use or animal use on such form as is mentioned in either sub-paragraph(*a*) or (*b*) of this paragraph on one or more occasions all such applications shall be deemed, for the purposes of this paragraph, to be a single application in respect of medicinal products for human use or animal use respectively on a form mentioned in the appropriate sub-paragraph.

(3) Any application made after 31st August 1977 for the renewal of a product licence of right which was granted for a period of 5 years shall be regarded, for the purpose of these regulations, as having been made in the licence year ending on 31st August 1977.".

Amendment to regulation 5 of the principal regulations

5.—(1) Regulation 5(5) of the principal regulations shall be amended in accordance with the following paragraph of this regulation and shall accordingly have effect as set out in Schedule 1 to these regulations.

(2) In regulation 5(5)(*b*) there shall be omitted after the words "the Medicines (Surgical Materials) Order 1971" the comma and the word "then", and after "1973", "1974", and "1975", in (*i*), (*ii*) and (*iii*) of sub-paragraph (*b*) there shall be inserted the word "then".

Amendment of regulation 7 of the principal regulations

6. In regulation 7(1) of the principal regulations after "£25" there shall be inserted the words "in respect of each description of medicinal product to which such product licence relates".

(a) S.I. 1974/832 (1974 II, p. 3241).

Amendment of regulation 11 *of the principal regulations*

7. For regulation 11 of the principal regulations there shall be substituted the following regulation:—

"**11.**—(1) Any person who is the holder of a product licence may notify the licensing authority of his intention to apply for the renewal of such licence in due course and may pay before 31st January 1977 an amount equivalent to the annual fee which would have become payable under the provisions of these regulations if he had made an application in the licence year ending on 31st August 1976 in relation to a licence of the same kind as that product licence.

(2) Where the holder of a product licence has made such a payment as is mentioned in paragraph (1) of this regulation before 31st January 1977 and subsequently makes an application for renewal of a product licence of the same kind in relation to a licence ending on a date after 31st August 1976 he shall be treated, for the purpose of these regulations, as if he had paid an annual fee in respect of the licence year ending on 31st August 1976.

(3) Any payment made by any person in accordance with the provisions of paragraph (1) of this regulation 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.

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

Amendment of regulation 20 *of the principal regulations*

8.—(1) In regulation 20(1) of the principal regulations at the end of sub-paragraph (*a*) there shall be inserted the words "but this sub-paragraph shall not apply in connection with any application made after 31st August 1976".

(2) After paragraph (4)(*b*) of regulation 20 of the principal regulations there shall be inserted the following—

"(*c*) Where annual fees have been paid 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 and annual fees are payable under these regulations in respect of the licence year ending on 31st August 1977 in respect of product licences of the same kind the amount of the annual fees payable shall not exceed £37,500, provided that payment of fees payable is made before 31st January 1977.

(*d*) Where annual fees have been paid 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 and annual fees are payable under these regulations in respect of the licence year ending on 31st August 1977 in respect of product licences of the same kind, the amount of the annual fees payable shall not exceed £12,500, provided that payment of fees payable is made before 31st January 1977.".

(3) Paragraphs (5) and (6) of regulation 20 of the principal regulations are hereby revoked.

Amendment of Part VI *of Schedule* 1 *to the principal regulations*

9.—(1) Part VI of Schedule 1 to the principal regulations shall be amended in accordance with the following paragraphs of this regulation and shall accordingly have effect as set out in Schedule 2 to these regulations.

(2) In paragraph 1 for the words from "the licence years ending on 31st August 1976" to the words "shall be disregarded" there shall be substituted the words "the licence year ending on 31st August 1976 the first £200,000 of such turnover shall be disregarded, and in relation to the licence year ending on 31st August 1977 the first £250,000 of such turnover shall be disregarded, but if the annual fee payable in respect of the licence year ending on 31st August 1977 is not paid—

(*a*) within the period of 2 months commencing on the date on which, by virtue of these regulations, the annual fee is payable, or

(*b*) if 31st January 1977 is later than the end of such period of 2 months, by 31st January 1977,

the first £250,000 of such turnover shall not be disregarded.".

(3) In Tables 1 and 2 opposite "1977" in the column headed "1977" for "0·25%" there shall be substituted "0·5%".

(4) In paragraph 3—

(*a*) in sub-paragraph (i), there shall be deleted all the words from "multiplied by" to the end of that sub-paragraph;

(*b*) in sub-paragraphs (ii) and (iii), there shall be deleted the words "multiplied as aforesaid".

(5) After paragraph 3 there shall be inserted the following paragraph—

"**4.** Where an applicant has paid an annual fee which became payable by virtue of these regulations in respect of the licence year ending on 31st August 1976, or has paid an amount equivalent to an annual fee in accordance with the provisions of regulation 11(1), the annual fee payable in respect of the licence year ending on 31st August 1977 shall be at the rate of 0·25 per cent in substitution for the rate specified in Table 1 or 2 of this Part of this Schedule.".

David Ennals,
Secretary of State for Social Services.

7th July 1976.

John Morris,
Secretary of State for Wales.

13th July 1976.

Bruce Millan,
Secretary of State for Scotland.

14th July 1976.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 14th July 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 16th day of July 1976.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 16th day of July 1976.

(L.S.)

R. Shaw,
Deputy Secretary.

We consent.

T. E. Graham,
Donald R. Coleman,
Two of the Lords Commissioners of Her Majesty's Treasury.

21st July 1976.

SCHEDULE 1 Regulation 5(1)

Containing regulation 5(5) of the principal regulations as amended by these regulations**(a)**

5.—(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

(a) The substitutions and additions made by these regulations are shown in italics.

of Substances for Manufacture) Order 1971 or the Medicines (Surgical Materials) Order 1971:—

(i) during the period between 1st September 1972 and 31st August 1973, *then* 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, *then* 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, *then* no additional sum shall be payable in accordance with the provisions of paragraph (4).

Regulation 9(1) SCHEDULE 2

Containing Part VI of Schedule 1 to the principal regulations as amended by these regulations**(a)**

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 year ending on 31st August 1976 the first £200,000 of such turnover shall be disregarded, and in relation to the licence year ending on 31st August 1977 the first £250,000 of such turnover shall be disregarded, but if the annual fee payable in respect of the licence year ending on 31st August 1977 is not paid—*

(a) within the period of 2 months commencing on the date on which, by virtue of these regulations, the annual fee is payable, or

(b) if 31st January 1977 is later than the end of such period of 2 months, by 31st January 1977,

the first £250,000 of such turnover shall not 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	—	0·5%	0·5%	0·5%	0·5%
1978	—	—	0·25%	0·5%	0·5%
1979	—	—	—	0·25%	0·5%
1980 or later	—	—	—	—	0·5%

(a) The substitutions and additions made by these regulations are shown in italics.

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	—	0·5%	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, 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, or

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

4. *Where an applicant has paid an annual fee which became payable by virtue of these regulations in respect of the licence year ending on 31st August 1976, or has paid an amount equivalent to an annual fee in accordance with the provisions of regulation 11(1), the annual fee payable in respect of the licence year ending on 31st August 1977 shall be at the rate of 0·25 per cent in substitution for the rate specified in Table 1 or 2 of this Part of this Schedule.*

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations amend the Medicines (Fees) Regulations 1976.
The main changes are—

(*a*) a new regulation 3A is added relating to renewal fees on the renewal of product licences of right;

(*b*) a new regulation is substituted for regulation 11 of the principal regulations which relates to the payment of annual fees in advance;

(*c*) amendments to regulation 20 provide that the concession in respect of the minimum annual fees contained in paragraph (1)(*a*) shall not apply in respect of applications made after 31st August 1976 and that annual fees in respect of the licence year ending on 31st August 1977 are fixed at a maximum of £37,500 and £12,500 in respect of medicinal products for human and animal use respectively;

(*d*) the rate in Tables 1 and 2 of Part VI of Schedule 1 at which annual fees are calculated in relation to applications made in the licence year ending on 31st August 1977 is increased from 0·25% to 0·5% but it is provided by paragraph 4 of Part VI of Schedule 1 (which supersedes regulation 20(6) which is revoked) that, where annual fees have been paid in the licence year ending on 31st August 1976 or are treated as having been paid in that year by virtue of regulation 11, the rate is 0·25%;

(*e*) the amount of annual turnover which is to be disregarded in calculating annual fees in the licence year ending 31st August 1977 is increased from £200,000 to £250,000 where payments are made within specified periods.

The other amendments are of a minor nature.

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