STATUTORY INSTRUMENTS

1977 No. 1374

MEDICINES

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

Made - - - -	*5th August* 1977
Laid before Parliament	*11th August* 1977
Coming into Operation	*1st September* 1977

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 section 1 (1) and (2) of the Medicines Act 1971(**a**) and now vested in them(**b**), and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following regulations, hereby make the following regulations:—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Fees) Amendment (No. 2) Regulations 1977 and shall come into operation on 1st September 1977.

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

Amendment of regulation 3 of the principal regulations

2. After paragraph (5) of regulation 3 of the principal regulations (product licences) there shall be inserted the following additional paragraphs—

"(6) Where an application for the grant of a product licence is in respect of two or more medicinal products having the same pharmaceutical form which consist of the same active ingredient in different strengths there shall be payable by the applicant a fee of £120 in respect of each different strength of the active ingredient in excess of one, in addition to any initial fee or review fee payable in accordance with the provisions of these regulations.

(7) Where, in connection with an application for the grant of a product licence, before the application is determined by the licensing authority the applicant notifies the authority that he desires to make a change in the particulars of the qualitative or quantitative composition of the medicinal product contained in the application or to make a

(**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 section 1(3) of, 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).
(**d**) S.I. 1976/1145, 1977/1056 (1976, II. p. 3123; 1977 II. p. 3012).

further change in such particulars there shall be payable by the applicant a fee of £120, in addition to any initial fee and any other fee payable by him in accordance with the provisions of these regulations."

Amendment of regulation 3A of the principal regulations

3. In regulation 3A of the principal regulations (renewal of licences of right)—

(*a*) in paragraph (1) for "£60" there shall be substituted "£120";

(*b*) in paragraph (2)(*a*) after the words "less than 5 years" there shall be inserted the words "there shall be payable by the applicant a renewal fee of £25";

(*c*) in paragraph (2)(*b*) after the words "respectively which have been renewed" there shall be inserted the words "there shall be payable by the applicant—

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

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

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

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

(*d*) after paragraph 2(*b*) there shall be omitted the words from "the renewal fee of £60 mentioned in paragraph (1)" to "a renewal fee of £25";

(*e*) after paragraph (3) there shall be inserted an additional paragraph—

(4) The Minister may waive payment of or reduce any renewal fee otherwise payable in accordance with the provisions of this regulation or, if such fee has been paid, refund it in whole or in part where an application for the renewal of a product licence relates to a medicinal product which falls within a class specified in Part II of Schedule 2.".

Amendment of regulation 6 of the principal regulations

4. In regulation 6 of the principal regulations (fees in respect of variations)—

(*a*) in paragraph (2), after the words "the active ingredients" there shall be inserted the words "strength of the active ingredients," and for "£25" there shall be substituted "£120";

(*b*) after paragraph (2) there shall be inserted an additional paragraph—

"(2A) in the preceding paragraph "change in strength" means—

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

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

(*c*) after paragraph (7) there shall be inserted the following paragraph—

"(8) The Minister may waive payment of or reduce any fee otherwise payable in accordance with the provisions of this regulation in relation to an application for the variation of a product licence or, if such fee has been paid, refund it in whole or in part—

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

(*b*) in a case where the medicinal product to which the application relates falls within a class specified in Part II of Schedule 1, or

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

(i) shortage of materials or

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

Additions to the principal regulations

5.—(1) The principal regulations shall be amended by the addition of the following regulation after regulation 6 thereof—

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

6A.—(1) Subject to the provisions of paragraph (2) below, where, in connection with the review by the licensing authority of the safety, quality and efficacy of substances or articles in respect of which product licences granted under Part II of the Act are in force, advice has been given to the licensing authority by a Committee established under section 4 of the Act in relation to a medicinal product of a description to which a product licence (in this regulation referred to as a " relevant licence") relates, an application is made—

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

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

(**a**) Section 24(1A) was added by regulation 4(4) of the Medicines (Medicines Act 1968 Amendment) Regulations 1977 (S.I. 1977/1050 and regulation 4(4) of the Medicines Act 1968 Amendment) Regulations (Northern Ireland) 1977.

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

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

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

there shall be payable by the applicant a fee of £120 (in this regulation referred to as "a review fee") in respect of—

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

(ii) where the application is in respect of two or more medicinal products which consist of the same active ingredient in different strengths, each different strength of the active ingredient

and, where any initial fee or any fee in connection with an application for variation would otherwise be payable by him in accordance with the provisions of these regulations, in substitution for such fee, provided that only one review fee shall be payable in respect of any application in respect of two or more medicinal products described in the same paragraph of Schedule 2.

(2) Where the applicant has previously paid an initial fee of £120 in accordance with the provisions of these regulations he shall not be liable to pay a review fee in accordance with the provisions of paragraph (1) above.

(3) Where the applicant has paid an initial fee of an amount less than £120, in accordance with these regulations or in accordance with regulations in force at the time when such fee became payable, the fee payable by him shall be an amount equal to the difference between £120 and the amount of the initial fee paid by him.

(4) The provisions of regulation 18(*c*) and paragraph 3 of Part VII of Schedule 1 shall have effect in relation to a review fee as if in that regulation and that paragraph any reference to an initial fee were a reference to a review fee.".

(2) The principal regulations shall be amended by the addition of the following regulation after regulation 15 thereof—

"*Late payment of annual fees*

15A.—(1) Where an annual fee has not been paid by the holder of the licence by the end of the period of three months from the due date a further fee, calculated in accordance with the provisions of the following paragraphs, shall be payable.

(2) The further fee referred to in the preceding paragraph shall be an amount equivalent to 1 per cent of the annual fee payable multiplied by the number of complete months contained in the period from the day

after the end of the period of three months from the due date until the date when the annual fee is paid, rounded down to the nearest £10. Where the annual fee payable is less than £10, no such fee shall be payable.

(3) Where the holder of a licence has not furnished evidence of his annual turnover in accordance with the provisions of Part V of Schedule 1 so that the annual fee payable in respect of a licence year cannot be determined before the due date, he may make a payment of any amount on account of the annual fee payable by him (in this regulation referred to as a "payment on account").

(4) Where the holder of a licence has made a payment on account in the circumstances mentioned in the preceding paragraph or a provisional payment in the circumstances mentioned in regulation 15, the further fee payable by him shall be calculated as if in paragraph (2) above the reference to the annual fee payable were to the difference between the payment on account, or the provisional payment, as the case may be, and the amount of the annual fee as subsequently determined.

(5) In this regulation—

(*a*) "due date" means the date upon which an annual fee became payable in accordance with the provisions of these regulations;

(*b*) references to a period calculated from a day are references to the period inclusive of that day."

Amendment of regulation 11 *of the principal regulations*

6. For paragraphs (1) and (2) of regulation 11 there shall be substituted the following paragraphs—

"(1) Any person who is the holder of a product licence may during the licence year ending on 31st August 1979 notify the licensing authority of his intention to apply for the renewal of that licence and at the time of such notification pay an amount equivalent to the annual fee which would have been payable if he had made an application for the renewal of that licence at that time.

(2) Where the holder of a product licence has made such a payment as is mentioned in paragraph (1) of this regulation he shall be treated for the purposes of paragraph 5 of Part IV of Schedule 1 and paragraphs 4 and 5 of Part VI of that Schedule as if he had made an application for the renewal of that licence at the time of such notification as is mentioned in paragraph (1) above and as if such payment had been the payment of an annual fee in respect of that application in the licence year ending on 31st August 1979.".

Amendment of regulation 18 *of the principal regulations*

7. In regulation 18 of the principal regulations (initial fees)—

(*a*) in paragraph (*a*) for "£1,800" there shall be substituted "£2,000";

(*b*) at the end of paragraph (*c*) for the full stop there shall be substituted a comma, and there shall be inserted the word "or";

(*c*) after paragraph (*c*) there shall be inserted the following additional paragraphs—

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

(i) at the time of the application for the grant of a product licence a person other than the applicant was the holder of, or an applicant for the grant of, a product licence in respect of the existing preparation and the particulars relating to the medicinal product contained in the application are the same in all respects as the corresponding particulars contained in the application in respect of the existing preparation, provided that the higher initial fee was paid in respect of the existing preparation, or

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

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

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

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

Amendment of Schedule 1 *to the principal regulations*

8.—(1) Part I of Schedule 1 to the principal regulations shall be amended in accordance with the following paragraph and shall accordingly have effect as set out in the Schedule to these regulations.

(2) In Part I of Schedule 1 to the principal regulations—

(*a*) in paragraphs 1(*a*) and 2(*a*) of column 2 for "£1,800" there shall be substituted "£2,000";

(*b*) in paragraphs 1(*b*) and 2(*b*) of column 2 for "£60" there shall be substituted "£120";

(*c*) in paragraphs 1 and 2 of column 3 the words "£50, or" and "whichever is the greater" shall be omitted;

(*d*) in paragraphs 3 and 4 of column 2 for "£50" there shall be substituted "£120",

(*e*) in paragraph 5(*c*) of column 2 after the words "terms of the licence" there shall be inserted the words "except in respect of premises in which manufacturing or assembly operations are also to be carried out under the terms of the licence".

(3) In Part III of Schedule 1—

(*a*) in paragraph 1 the word "either" shall be omitted, and for sub-paragraph (*b*) there shall be substituted the following sub-paragraphs—

"(*b*) that any patent granted in respect of the existing preparation under the Patents Act 1949(**a**) has expired or has ceased to have effect for the period of one year ending on the date of the application for the grant of the product licence, and

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

(*b*) in paragraph 4 the word "or" at the end of sub-paragraph (*a*) and the whole of sub-paragraph (*b*) shall be omitted.

(4) In Part VI of Schedule 1—

(*a*) at the beginning of paragraph 1 there shall be inserted the words "Subject to the provisions of paragraph 2A below,";

(*b*) for Tables 1, 2 and 3 in paragraph 1 there shall be substituted the following tables—

(**a**) 1949 c. 87.

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	—	—	0.75%	1.0%	1.25%
1979	—	—	—	1.0%	1.25%
1980 or later	—	—	—	—	1.25%

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	—	—	0.75%	1.0%	1.25%
1979	—	—	—	1.0%	1.25%
1980 or later	—	—	—	—	1.25%

TABLE 3

MANUFACTURER'S LICENCES AND WHOLESALE DEALER'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	—	0.075%	0.1%	0.1%
1979	—	—	0.1%	0.1%
1980 or later	—	—	—	0.1%

(*c*) after paragraph 2 there shall be inserted an additional paragraph—

"2A— (*a*) Where in the licence year ending on 31st August 1978 the licence holder submits evidence to the satisfaction of the Minister that his turnover in relation to the calendar year which ended on 31st December 1976 is—

(i) less than £100,000 the annual fee payable in respect of that licence year shall be £100,

(ii) £100,000 or more but less than £200,000, the annual fee payable in respect of that licence year shall be the sum of £100 and 0·4 per cent of that part of his turnover which is more than £100,000.".

(*d*) for paragraph 4 there shall be substituted the following paragraph—

"4. Where an applicant has paid an annual fee which became payable by virtue of these regulations or an amount equivalent to an annual fee in accordance with the provisions of regulation 11(1) and the application is made before 1st September 1977 the annual fee payable for the licence year ending 31st August 1978, or where the application is made after 1st September 1977 the annual fee payable in respect of the licence year in which the application is made, as the case may be, shall be—

(*a*) where the licence is a product licence for a medicinal product for human use, at the rate of 0·25 per cent in substitution for the rate specified in Table 1 of this Part of this Schedule, or

(*b*) where the licence is a product licence for a medicinal product for animal use, at the rate of 0·25 per cent in substitution for the rate specified in Table 2 of this Part of this Schedule, or

(*c*) where the licence is a manufacturer's licence or a wholesale dealer's licence, at the rate of 0·025 per cent in substitution for the rate specified in Table 3 of this Part of this Schedule,"

(*e*) after paragraph 4 there shall be inserted the following paragraphs—

"5. Where an annual fee has been paid in accordance with these regulations and the application is made before 1st September 1977 the annual fee payable for the licence year ending 31st August 1978, or where the application is made after 1st September 1977 the annual fee payable in respect of the licence year in which the application is made shall not exceed—

(*a*) where the product licences relate to medicinal products for human use, £50,000, or

(*b*) where the product licences relate to medicinal products for animal use, £16,500.

6. (*a*) Where the Minister is satisfied that during the period from 1st September 1975 until the end of the licensing year which immediately precedes the beginning of the licence year in which an application is made—

(i) an applicant for the grant of a product licence has not, in the course of a business carried on by him, sold or supplied any medicinal product which is subject to the restrictions imposed by section 7 of the Act; or

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

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

that applicant shall be treated, for the purpose of paragraph 4 of this Part of this Schedule as if he had paid an annual fee in respect of the licence year immediately preceding the year in which the application is made.

(*b*) Where the Minister is satisfied that such sale or supply, manufacture or assembly, or sale or offer for sale by way of wholesale dealing or distribution otherwise than by way of sale as is mentioned in sub-paragraph (*a*) above was exempt from the restrictions imposed by section 7, section 8(2) or section 8(3) 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 sub-paragraph (*a*) shall apply as if no such sale or supply, or manufacture or assembly, or sale or offer for sale by way of wholesale dealing or distribution otherwise than by way of sale had taken place during the relevant period.

7. Notwithstanding the provisions of the preceding paragraphs of this Part of this Schedule the minimum annual fee payable by an applicant for a licence shall be—

(1) in the case of a product licence—

(*a*) where the application was made between 6th March 1976 and 31st August 1977 the sum of £100 or 0·5 per cent of turnover, whichever is the lower, but in no case shall the fee be less than £50, or

(*b*) where the application was made on or after 1st September 1977 the sum of £200, except where the applicant has paid an annual fee under these regulations for the licence year ending 31st August 1977, when the fee shall be £100;

(2) in the case of a manufacturer's licence or wholesale dealer's licence, where the application is made after 1st September 1977, twice the amount of the minimum flat rate fee specified in Part I of this Schedule unless—

(*a*) the applicant has paid an annual fee under these regulations for the licence year ending 31st August 1977, or

(*b*) the Minister is satisfied that the provisions of paragraph 6 of this Part of this Schedule apply."

(5) In Part VII of Schedule 1—

(*a*) in paragraphs 1 and 2 for "£10,000" there shall be substituted "£20,000",

(*b*) for paragraph 3 there shall be substituted the following—

"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 of such fees in any one licence year—

(*a*) where the gross value of goods sold or supplied or services rendered during such a period as is mentioned in paragraphs 1 and 2 was less than £10,000, shall not exceed £50;

(*b*) where the gross value of goods sold or supplied or services rendered during such a period as is mentioned in paragraphs 1 and 2 was £10,000 or more but less than £20,000, shall not exceed £100.".

David Ennals,
Secretary of State for Social Services.

26th July 1977.

John Morris,
Secretary of State for Wales.

27th July 1977.

Bruce Millan,
Secretary of State for Scotland.

27th July 1977.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 28th July 1977.

John Silkin,
Minister of Agriculture, Fisheries and Food.

(L.S.)

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 1st day of August 1977.

N. Dugdale,
Permanent Secretary.

(L.S.)

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 2nd day of August 1977.

W. H. Jack,
Deputy Secretary.

(L.S.)

We consent.

T. E. Graham,
David Stoddart,
Two of the Lords Commissioners of
Her Majesty's Treasury.

5th August 1977.

Regulation 8(1) SCHEDULE

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

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*) *£2,000*, or (*b*) *£120*, 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. An amount calculated in accordance with Parts IV, V and VI of this Schedule, 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*) *£2,000* or (*b*) *£120*, 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. An amount calculated in accordance with Parts IV, V and VI of this Schedule, except in relation to an application to which paragraphs 1 or 2 of Part VII of this Schedule applies.
3. Clinical trial certificate	3. *£120*, except in relation to an application to which paragraph 4 of Part VII of this Schedule applies.	3. Nil.
4. Animal test certificate	4. *£120*, 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)	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

(a) The words substituted or added by these regulations are shown in italics.

Column 1 Kind of licence or certificate	Column 2 Initial fee	Column 3 Annual fees
	operations are to be carried out under the terms of the licence, and (*c*) £10 for each set of premises in which medicinal products are to be stored for distribution under the terms of the licence *except in respect of premises in which manufacturing or assembly operations are also to be carried out under the terms of the licence.* (Subject to the provisions of paragraph 3 of Part VII of this Schedule).	application to which paragraphs 1, 2 or 6 of Part VII of this Schedule applies.
6. Wholesale dealer's licence not being a licence to which the following paragraph applies.	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.
7. Wholesale dealer's licence which relates to imported proprietary products and is subject to the provisions of paragraph 8 of Schedule 3 to the Standard Provisions Regulations.	7. £50 for each separate set of premises in which any functions specified in paragraph 8(3) of Schedule 3 to the Standard Provisions Regulations are to be carried out in relation to imported proprietary products to which the licence relates or £10 for each separate set of premises in which medicinal products to which the licence relates are or are to be stored, whichever amount is the greater.	7. The amount specified in paragraph 7 of column 2, or an amount calculated in accordance with Parts IV, V or VI of this Schedule, whichever is the greater, except in relation to an application to which paragraph (1) or (2) of Part VII of this Schedule applies.

EXPLANATORY NOTE

(*This* Note *is not part of the Regulations.*)

These Regulations further amend the Medicines (Fees) Regulations 1976 (the "principal Regulations").

The main changes are—

(*a*) increases in both the higher and lower initial fees payable for product licences;

(*b*) increases in the fees payable upon the variation of a product licence, a manufacturer's licence and a wholesale dealer's licence;

(*c*) increases in the fees payable for a clinical trial certificate and an animal test certificate;

(*d*) the introduction, by the addition of regulation 6A to the principal Regulations, of fees payable by the holder of a licence of right where an application is made for a product licence;

(*e*) the introduction, by the addition of regulation 15A to the principal Regulations, of further fees payable where the holder of a licence has not paid the annual fee by the due date;

(*f*) provisions for the reduction of the higher initial fee payable where certain conditions are satisfied (regulation 7); and

(*g*) the substitution of new tables for the calculation of annual fees for product licences and manufacturer's and wholesale dealer's licences (regulation 8(3)).

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