STATUTORY INSTRUMENTS

1980 No. 1126

MEDICINES

The Medicines (Fees) Amendment (No. 2) Regulations 1980

Made - - - -	30*th July* 1980
Laid before Parliament	8*th August* 1980
Coming into Operation	1*st September* 1980

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and 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) 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. These regulations, which may be cited as the Medicines (Fees) Amendment (No. 2) Regulations 1980, amend the Medicines (Fees) Regulations 1978(**c**) (hereinafter referred to as "the principal regulations") and shall come into operation on 1st September 1980.

Amendment of regulation 1 of the principal regulations

2. In regulation 1 of the principal regulations (interpretation)—

(*a*) in paragraph (1)—

(i) in the definition of "application", after "authority" there is inserted "or board" and for "National Health Service (Scotland) Act 1972" there is substituted "National Health Service (Scotland) Act 1978"(**d**), and

(ii) the definition of "standard amount" is deleted; and

(**a**) 1971 c. 69.

(**b**) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388), in the case of the Secretary of State concerned with agriculture in Wales by virtue of Article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272), and in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36), and section 1(3) of, and paragraph 2(1)(*b*) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(**c**) S.I. 1978/1121, amended by S.I. 1979/899 and 1980/16.

(**d**) 1978 c. 29.

(*b*) immediately after paragraph (2) there is inserted the following paragraph:

"(2A) In these regulations references to the higher alternative amount, the standard amount and the lower alternative amount are to the amounts specified respectively as such amounts in column 2 of Table A.".

Amendment of regulation 2 of the principal regulations

3. In regulation 2 of the principal regulations (fees for product licences) after paragraph (3) there is inserted the following paragraph:

"(3A) The amount of each capital fee payable under paragraph (3) shall be—

(*a*) where the medicinal product falls within a class specified in Part II of Schedule 1 or the conditions specified in Part III of Schedule 1 are fulfilled, the standard amount, and

(*b*) in every other case, the higher alternative amount.".

Amendment of regulation 4(3) of the principal regulations

4. In regulation 4(3) of the principal regulations (capital fees for renewal of manufacturer's and wholesale dealer's licences) for "as the basic rate in whichever of paragraphs 3(*a*), 3(*b*), 3(*c*), 4 or 5 of column 3 of Table A is appropriate" there is substituted "in column 2 of paragraph 3, 4 or 5, as appropriate, of Table A".

Amendment of regulation 6 of the principal regulations

5.—(1) Regulation 6 of the principal regulations (capital fees for variation of licences) is amended in accordance with the following paragraphs of this regulation.

(2) In paragraph (6) (manufacturer's and wholesale dealer's licences) for "equal to the amount shown in whichever of paragraphs 3(*a*), 3(*b*), 3(*c*) or 5 of column 3 of Table A is appropriate" there is substituted "of the amount shown in column 2 of paragraph 3 or 5, as appropriate, of Table A in connection with the additional or different premises or the premises of which the use is to be varied".

(3) In paragraph (8) (wholesale dealer's (import) licences) for "equal to the amount shown as the basic rate in column 3" there is substituted "of the amount shown in column 2".

Amendment of Part I of Schedule 1 to the principal regulations

6.—(1) In Part I of Schedule 1 to the principal regulations column 2 of Table A (capital fees) is amended in accordance with the following paragraphs of this regulation and Table A shall have effect accordingly as set out in the Schedule to these regulations.

(2) For the entries in paragraphs 1 (product licences—human use) and 2 (product licences—veterinary use) there is substituted in each case the following:

"(*a*) *Higher alternative amount*—£2,750

(*b*) *Standard amount*—£200

(*c*) *Lower alternative amount*—£40.".

(3) In paragraph 3 (manufacturer's licences) for "An amount equal to the basic rate as determined in column 3" there is substituted the following:

"(*a*) £130 for each set of premises in which manufacturing operations are to be carried out under the terms of the licence and (*b*) £65 for each set of premises in which assembly (but not manufacturing) operations are to be carried out under the terms of the licence and (*c*) £15 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.".

(4) In paragraph 4 (wholesale dealer's (import) licences) for "An amount equal to the basic rate as determined in column 3" there is substituted the following:

"£65 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 £15 for each separate set of premises in which medicinal products to which the licence relates are to be stored, whichever amount is the greater.".

(5) In paragraph 5 (wholesale dealer's licences) for "An amount equal to the basic rate as determined in column 3" there is substituted the following:

"£15 for each separate set of premises in which medicinal products to which the licence relates are to be stored.".

(6) In paragraphs 6 (clinical trial certificates) and 7 (animal test certificates) for "£150" there is substituted in each case "£200".

(7) In paragraph 8 (export certificates) for "£4" there is substituted "£5".

Patrick Jenkin,
Secretary of State for Social Services.

10th July 1980.

Nicholas Edwards,
Secretary of State for Wales.

17th July 1980.

George Younger,
Secretary of State for Scotland.

18th July 1980.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 23rd July 1980.

(L.S.)

Peter Walker,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 25th day of July 1980.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 25th day of July 1980.

(L.S.)

J. A. Young,
Permanent Secretary.

We consent,

Carol Mather,
J. A. Douglas-Hamilton,
Two of the Lords Commissioners of Her Majesty's Treasury.

30th July 1980.

Regulation 6

SCHEDULE

TABLE A IN THE PRINCIPAL REGULATIONS AS AMENDED BY THESE REGULATIONS(a)

TABLE A

Column 1 Kind of licence or certificate	Column 2 Capital Fees	Column 3 ANNUAL FEES		
		Basic rate	Standard percentage	Alternative percentage
1. Product licence (products for human use)	(*a*) *Higher alternative amount*—**£2,750** (*b*) *Standard amount*—**£200** (*c*) *Lower alternative amount*—**£40**	£125	0·28 (Calculated in accordance with Parts IV, V and VI except in relation to an application to which Part VII applies.)	(*a*) *First year* Licence year 1978/9: 1·0 Licence year 1979/80 and subsequent licence years: 1·25 (*b*) *Second or subsequent year:* 0·5
2. Product licence (products for veterinary use)	(*a*) *Higher alternative amount*—**£2,750** (*b*) *Standard amount*—**£200** (*c*) *Lower alternative amount*—**£40**	£125	0·28 (Calculated in accordance with Parts IV, V and VI except in relation to an application to which Part VII applies.)	(*a*) *First year* Licence year 1978/9:1·0 Licence year 1979/80 and subsequent licence years: 1·25 (*b*) *Second or subsequent year:* 0·5

(a) Words substituted by these regulations are shown in **bold type.**

Column 1 Kind of licence or certificate	Column 2 Capital fees	Column 3 ANNUAL FEES Basic rate	Standard percentage	Alternative percentage
3. Manufacturer's licence	(*a*) **£130 for each set of premises in which manufacturing operations are to be carried out under the terms of the licence and** (*b*) **£65 for each set of premises in which assembly (but not manufacturing) operations are to be carried out under the terms of the licence and** (*c*) **£15 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.**	(*a*) £100 for each set of premises in which manufacturing operations are to be carried out under the terms of the licence and (*b*) £50 for each set of premises in which assembly (but not manufacturing) operations are to be carried out under the terms of the licence and (*c*) £10 for each set of premises in which medicinal products are to be stored for distribution under the terms of the licence 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 Part VII.)	0·025 (Calculated in accordance with Parts IV, V and VI except in relation to an application to which Part VII applies.)	(*a*) *First year* Licence year 1978/9: 0·1 Licence year 1979/80 and subsequent licence years: 0·125 (*b*) *Second or subsequent years:* 0·05

4. Wholesale dealer's (import) licence	**£65 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 £15 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.**	£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.	0·025 (Calculated in accordance with Parts IV, V and VI except in relation to an application to which Part VII applies.)	(*a*) *First year* Licence year 1978/9: 0·1 Licence year 1979/80 and subsequent licence years: 0·125. (*b*) *Second or subsequent* years: 0·05
5. Wholesale dealer's licence other than a wholesale dealer's (import) licence	**£15** for each separate set of premises in which medicinal products to which the licence relates are to be stored.	£10 for each separate set of premises in which medicinal products to which the licence relates are to be stored.	NIL	NIL
6. Clinical trial certificate	**£200,** except in relation to an application to which paragraph 3 of Part VII applies.	NIL	NIL	NIL
7. Animal test certificate	**£200,** except in relation to an application to which paragraph 4 of Part VII applies.	NIL	NIL	NIL
8. Export certificate	**£5**	NIL	NIL	NIL

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These regulations further amend the Medicines (Fees) Regulations 1978 which provide for the fees payable in connection with licences granted and certificates issued under the Medicines Act 1968. The changes made by these regulations are—

(*a*) to increase the amounts of capital fees payable upon the grant, renewal and variation of product licences, manufacturer's licences and wholesale dealer's licences and upon the grant of clinical trial certificates, animal test certificates and export certificates;

(*b*) to make clear that on an application for the grant of a product licence, the capital fee is, except in certain circumstances specified in the 1978 regulations, the higher alternative amount (increased to £2,750); and

(*c*) minor drafting and textual amendments.