
 S T A T U T O R Y I N S T R U M E N T S

1982 No. 1121**MEDICINES****The Medicines (Fees) Amendment Regulations 1982**

<i>Made</i> - - - - -	<i>3rd August 1982</i>
<i>Laid before Parliament</i>	<i>11th August 1982</i>
<i>Coming into Operation</i>	<i>1st September 1982</i>

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 these regulations pursuant to section 129(6) of the Medicines Act 1968(c), hereby make the following regulations:—

Citation, interpretation and commencement

1. These regulations, which may be cited as the Medicines (Fees) Amendment Regulations 1982, amend the Medicines (Fees) Regulations 1978(d) (hereinafter referred to as “the principal regulations”) and shall come into operation on 1st September 1982.

Amendment of regulation 1 of the principal regulations

2. For paragraph (2A) of regulation 1 of the principal regulations there shall be substituted the following paragraph—

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

(a) 1971 c.69.

(b) In the case of the Secretaries of State concerned with health in England and 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) 1968 c.67.

(d) S.I. 1978/1121, amended by S.I. 1979/899, 1980/16, 1126.

Amendment of regulation 6 of the principal regulations

3. In paragraph (9) of regulation 6 of the principal regulations, the words “In addition to the fees (if any) payable in accordance with the preceding paragraphs,” shall be omitted.

Amendment of regulation 14 of the principal regulations

4. In regulation 14 of the principal regulations, the words “or the issue of a certificate, or the variation of a licence, as the case may be” shall be omitted.

Amendment of Table A of Part I of Schedule 1 to the principal regulations

5.—(1) Table A of Part I of Schedule 1 to the principal regulations shall be amended in accordance with the following provisions of this regulation and shall have effect in the principal regulations as set out in the Schedule to these regulations.

(2) For the entries in column 2 of paragraphs 1 (product licences—human use) and 2 (product licences—veterinary use) there shall be substituted in each case the following—

- “(a) *Higher alternative amount—£2,500*
- “(b) *Standard amount—£150*”.

(3) For the entries in column 2 of paragraphs 3 (manufacturer’s licence), 4 (wholesale dealer’s (import) licence) and 5 (wholesale dealer’s licence other than a wholesale dealer’s (import) licence) there shall be substituted in each case the word “NIL”.

(4) Paragraphs 6 (clinical trial certificate), 7 (animal test certificate) and 8 (export certificate) of the Table shall be omitted.

Amendment of Table B of Part I of Schedule 1 to the principal regulations

6. Paragraphs 1 and 3 of Table B of Part I of Schedule 1 to the principal regulations shall be omitted.

Amendment of Schedule 3 to the principal regulations

7. In Schedule 3 to the principal regulations, in paragraph 2 the words “or to issue or renew a certificate” and in paragraph 8 the words “or certificate” shall be omitted.

Revocations

8. Regulations 3, 4(2) and (3), 5, 6(1) to (8), 7, 8, 9 and 11 of the principal regulations; paragraphs 3 and 4 of Part VII of Schedule 1 thereto; and paragraphs 2(b) and (f) of Schedule 4 thereto are hereby revoked.

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

K. Clarke,
Minister of State,
Department of Health and Social Security.

22nd July 1982.

Nicholas Edwards,
Secretary of State for Wales.

27th July 1982.

George Younger,
Secretary of State for Scotland.

28th July 1982.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 29th July 1982.

(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 29th day of July 1982.

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

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 30th day of July 1982.

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

We consent.

Geoffrey Howe,
John Selwyn Gummer,
Two of the Lords Commissioners of
Her Majesty's Treasury.

3rd August 1982.

Regulation 5(1)

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) <i>Higher alternative amount— £2,500</i> (b) <i>Standard amount—£150</i>	£125	0.28	(a) <i>First year Licence year 1978/9: 1.0 Licence year 1979/80 and subsequent licence years: 1.25</i> (b) <i>Second or subsequent year : 0.5</i> (Calculated in accordance with Parts IV, V and VI except in relation to an application to which Part VII applies.)
2. Product licence (products for veterinary use)	(a) <i>Higher alternative amount— £2,500</i> (b) <i>Standard amount—£150</i>	£125	0.28	(a) <i>First year Licence year 1978/9: 1.0 Licence year 1979/80 and subsequent licence years: 1.25</i> (b) <i>Second or subsequent year: 0.5</i> (Calculated in accordance with Parts IV, V and VI except in relation to an application to which Part VII applies.)

^(a) The amendments made 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	NIL	(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) <i>First year</i> Licence year 1978/9: 0.1 Licence year 1979/80 and subsequent licence years: 0.125 (b) <i>Second or subsequent years:</i> 0.05

Column 1 Kind of licence or certificate	Column 2 Capital fees	Column 3 ANNUAL FEES		
		Basic rate	Standard percentage	Alternative percentage
4. Wholesale dealer's (import) licence	NIL	£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) <i>First year</i> Licence year 1978/9: 0.1 Licence year 1979/80 and subsequent licence years: 0.125. (b) <i>Second or subsequent years:</i> 0.05
5. Wholesale dealer's licence other than a wholesale dealer's (import) licence	NIL	£10 for each separate set of premises in which medicinal products to which the licence relates are to be stored.	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. These Regulations reduce the capital fees payable for product licences by varying the higher alternative amount to £2,500 and the standard amount to £150 and they omit the lower alternative amount. The Regulations abolish capital fees for the renewal of product licences of right, for manufacturers' licences, wholesale dealers' licences, export certificates, clinical trial and animal test certificates and for variations of licences. The Regulations also make certain minor consequential amendments to the 1978 Regulations.

SI 1982/1121
ISBN 0-11-027121-1



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