

1987 No. 1439

**MEDICINES**

**The Medicines (Fees) Amendment Regulations 1987**

*Made* - - - - - *10th August 1987*

*Laid before Parliament* *11th August 1987*

*Coming into force* *1st September 1987*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Scotland and in Wales, 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)(a) 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 1987, amend the Medicines (Fees) Regulations 1978(d) (hereinafter referred to as "the principal Regulations") and shall come into force on 1st September 1987.

**Insertion in the principal Regulations of regulation 4A**

2. After regulation 4 of the principal Regulations there is inserted the following regulation—

**"Capital fees for variations**

4A.—(1) Subject to the following provisions of this regulation a capital fee of £75 shall be payable by the applicant in connection with each application for the variation of one or more of the provisions of a product licence granted under Part II of the Act unless such application is made at the specific invitation of the licensing authority.

(2) The provisions of paragraph (1) shall not apply in the case of an application for variation which is made by an authority or board constituted under the National Health Service Act 1977(e), the National Health Service (Scotland) Act 1978(f) or

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(a) 1971 c.69. By virtue of section 1(3) the expression "the Ministers" has the same meaning as in section 1(1) of the Medicines Act 1968 (c.67).

(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) 1968 c.67; section 129(6) has effect by virtue of the Medicines Act 1971, section 1(3)(b).

(d) S.I. 1978/1121; relevant amending instruments are S.I. 1979/899, 1980/16, 1126, 1982/1121 and 1985/1231.

(e) 1977 c.49.

(f) 1978 c.29.

the Health and Personal Social Services (Northern Ireland) Order 1972(a)".

**Amendment of regulation 14 of the principal Regulations**

3. In regulation 14 of the principal Regulations (time for payment of capital fees) there is inserted after the word "grant" the words ",or as the case may be, the variation,".

**Amendment to Table A of Part I of Schedule 1 to the principal Regulations**

4.—(1) Table A of Part I of Schedule 1 to the principal Regulations (types and levels of fees), is amended in accordance with the following provisions of this regulation.

(2) For each entry in Column 2 (Capital Fees), of the sum "£2,500" there is substituted the sum "£4,000".

(3) For each entry in Column 2 of the sum "£150" there is substituted the sum "£250".

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

22nd July 1987

*Tony Newton*  
Minister of State,  
Department of Health and Social Security

10th August 1987

*Wyn Roberts*  
Minister of State for Wales

10th August 1987

*Ian Lang*  
Minister of State,  
Scottish Office

In Witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 10th August 1987.



*John MacGregor*  
Minister of Agriculture, Fisheries and Food

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 6th day of August 1987.



*G. Buchanan*  
Under Secretary

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 6th day of August 1987.



*W. H. Jack*  
Permanent Secretary

We consent,

10th August 1987

*Peter Lloyd*  
*Michael Neubert*  
Two of Lords Commissioners of Her Majesty's Treasury

(a) S.I. 1972/1256 (N.I. 14).

## **EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations further amend the Medicines (Fees) Regulations 1978 ("the principal Regulations") which provide for the fees payable in connection with licences granted and certificates issued under the Medicines Act 1968.

Regulation 2 introduces a capital fee of £75 for the variation of a product licence granted under Part II of the Medicines Act 1968. Only one fee is payable for an application to vary one or more of the provisions of a licence made on one occasion. Certain public bodies exempt from having to pay fees for the grant of a product licence under the principal Regulations are likewise exempted from having to pay this fee.

Regulation 3 provides that this fee be paid on the application for variation.

Regulation 4 amends Column 2 of Part I of Schedule 1 to the principal Regulations by increasing the amount of capital fees payable for the grant of product licences for medicinal products for human and veterinary use. The standard amount of capital fees payable is increased from £150 to £250 and the higher alternative amount (payable in circumstances specified in the principal Regulations) is increased from £2,500 to £4,000.