

1989 No. 684

**FEES AND CHARGES**

**The Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Order 1989**

*Made* - - - - 17th April 1989  
*Coming into force* - 18th April 1989

Whereas a draft of this Order has been approved by a resolution of the House of Commons in pursuance of section 102(5) of the Finance (No. 2) Act 1987(a):

Now, therefore, the Secretaries of State for Health, for Wales, for Scotland and for Northern Ireland and the Minister of Agriculture, Fisheries and Food, being the Ministers of the Crown determined by the Treasury to be the appropriate authority in relation to the power to fix fees under section 1(1) of the Medicines Act 1971(b) acting jointly in exercise of the powers conferred by section 102 of the Finance (No. 2) Act 1987, hereby make the following Order:—

**Citation, commencement and interpretation**

1.—(1) This Order may be cited as the Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Order 1989 and shall come into force on the day after the day on which it is made.

(2) In this Order—

“the 1968 Act” means the Medicines Act 1968(c);

“the 1971 Act” means the Medicines Act 1971(d);

“the 1987 Act” means the Finance (No. 2) Act 1987;

“medicinal product” includes any substance or article specified in any order made under section 104 or 105(1)(a) of the 1968 Act which directs that Part II of that Act shall have effect in relation to such substance or article;

and other expressions have the same meaning as in the 1968 Act.

**Functions the costs of which are to be taken into account in fixing fees under the 1971 Act**

2. In relation to the power of the Ministers under section 1(1) of the 1971 Act to make regulations providing for the payment of such fees as are prescribed by the regulations with regard to the matters specified in that subsection, the functions specified for the purpose of section 102(3) of the 1987 Act are, as respects matters relating to medicinal products for human use, those functions set out in Schedule 1 to this Order.

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(a) 1987 c.51.

(b) See section 102(2)(b) of the Finance (No. 2) Act 1987.

(c) 1968 c.67.

(d) 1971 c.69, as amended by section 21 of the Health and Medicines Act 1988 (c.49).

**Matters to be taken into account in determining the costs of functions specified in Schedule 1 hereto**

3. In relation to each of the functions specified by article 2 of, and Schedule 1 to, this Order for the purposes of section 102(3) of the 1987 Act, the matters specified for the purposes of section 102(4) of that Act are those set out in Schedule 2 to this Order.

Signed by authority of the Secretary of State for Health

13th April 1989

*D. Mellor*  
Minister of State,  
Department of Health

12th April 1989

*Peter Walker*  
Secretary of State for Wales

12th April 1989

*Malcolm Rifkind*  
Secretary of State for Scotland

17th April 1989

*Tom King*  
Secretary of State for Northern Ireland

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereto affixed on 13th April 1989.



*John MacGregor*  
Minister of Agriculture, Fisheries and Food

**SCHEDULE 1**

Article 2

**FUNCTIONS THE COSTS OF WHICH ARE TO BE TAKEN INTO ACCOUNT  
IN FIXING FEES UNDER THE 1971 ACT**

1. Functions of the Ministers under Parts I, II, III, V, VI and, subject to paragraph 11 below, VIII of the 1968 Act and under the 1971 Act.
2. Functions of the Licensing Authority under Part II of the 1968 Act.
3. Functions (except those under Part VII of the 1968 Act) of the Medicines Commission established under section 2 of the 1968 Act.
4. Functions of the following Committees established under section 4 of the 1968 Act: the Committee on Safety of Medicines, the Committee on Review of Medicines and the Committee on Dental and Surgical Materials.
5. Functions of the Ministers or the Licensing Authority in relation to anything done by the European Communities or any of their institutions with respect to the control of medicinal products.
6. Functions of the Ministers or the Licensing Authority in relation to anything done by the World Health Organisation with respect to the control of medicinal products.
7. Without prejudice to paragraphs 5 and 6, functions of the Ministers or the Licensing Authority arising under any international instrument relating to the control of medicinal products.

8. Functions of persons appointed under the 1968 Act.

9. Functions of the Medicines Testing Laboratory of the Royal Pharmaceutical Society of Great Britain under arrangements made with Ministers in respect of work relating to enforcement of the 1968 Act.

10. Without prejudice to the generality of the foregoing paragraphs, the following functions of the Ministers:-

- (a) review of the functioning of the laws relating to the control of medicinal products (including whether or not a product or class of articles or substances should be made subject to such control) and development of proposals for legislation relating thereto;
- (b) maintenance of relations with persons and organisations both within the United Kingdom and abroad in respect of matters relating to the control of medicinal products;
- (c) subject to paragraph 11 below, enforcement of the 1968 Act and regulations and orders made under it, including investigation and prosecution of offences thereunder;
- (d) the conduct of civil proceedings for the recovery of debt arising in relation to any of the functions otherwise specified in this Schedule.

11. Paragraphs 1 and 10(c) above do not apply to the function of Ministers under the 1968 Act to enforce that Act and regulations and orders made under it in so far as that function consists of the enforcement of provisions relating to the retail sale, or supply in circumstances corresponding to retail sale, of medicinal products.

## SCHEDULE 2

Article 3

### MATTERS TO BE TAKEN INTO ACCOUNT IN DETERMINING THE COST OF FUNCTIONS SPECIFIED IN SCHEDULE 1

1. All costs (including capital costs) incurred by the Ministers, the Licensing Authority, the Medicines Commission, the Committees established under section 4 of the 1968 Act specified in paragraph 4 of Schedule 1 above, appointed persons referred to in paragraph 8 of Schedule 1 above, and the Royal Pharmaceutical Society of Great Britain which are directly attributable to the functions specified in Schedule 1 above.

2. That proportion of the costs (including capital costs), not falling within paragraph 1 above, incurred by or on behalf of any of the persons or organisations specified in paragraph 1 above in relation to staff, equipment, premises, facilities and matters connected therewith (whether directly or indirectly), being the proportion which falls to be attributed to any of the functions specified in Schedule 1 above.

3.—(1) In so far as the capital cost of any capital asset employed wholly by any of the persons or organisations referred to in paragraph 1 above in relation to any of the functions specified in Schedule 1 to this Order has not been taken into account under that paragraph, an allowance, calculated in accordance with sub-paragraph (3) below for depreciation of that asset.

(2) In so far as the capital cost of any capital asset employed partly by any of the persons or organisations referred to in paragraph 1 above in relation to any of the functions specified in Schedule 1 to this Order has not been taken into account under paragraph 2 above, an allowance, calculated in accordance with sub-paragraph (3) below for depreciation of that asset.

(3) The allowance for depreciation of a capital asset referred to in sub-paragraphs (1) and (2) above shall be calculated at a rate which takes into account the anticipated useful future life of the asset in question and the current replacement cost of that asset.

4. A return on the resources employed in carrying out any of the functions specified in Schedule 1 above.

5. The allocation of a sum in respect of matters which would otherwise be covered by insurance, the allocation of a sum in respect of superannuation payments and provision for bad debts in relation to any of the functions specified in Schedule 1 above.

6. The recovery of any past deficits in relation to any of the functions specified in Schedule 1 above.

7. The allocation over a period of years of an initial or exceptional cost in relation to any of the functions specified in Schedule 1 above.

8. In respect of any function of any of the persons or organisations specified in paragraph 1 above consisting of the payment or remittance of any sum or amount, both the sum or amount in question and the cost incurred in effecting the payment or remittance.

## **EXPLANATORY NOTE**

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

This Order specifies functions and matters which are to be taken into account in the determination of the fees prescribed under the Medicines Act 1971 in respect of applications for, variations or renewals of, or inspections related to, licences, certificates or directions for medicinal products under Part II of the Medicines Act 1968.

**90p net**

**ISBN 0 11 096684 8**

Printed in the United Kingdom for Her Majesty's Stationery Office

880 WO750 C22 4/89 452/3 4235 46378 891231K