STATUTORY INSTRUMENTS

## 1995 No. 871

# **FEES AND CHARGES**

The Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Amendment Order 1995

| Made   | -    | -     | - | - |   | 23rd March 1995 |
|--------|------|-------|---|---|---|-----------------|
| Coming | into | force | 2 | - | - | lst April 1995  |

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(1):

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(2) 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) Amendment Order 1995 and shall come into force on 1st April 1995.

(2) In this Order, "the principal Order" means the Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Order 1989(**3**).

#### Amendment of Schedule 1 to the principal Order

2. In Schedule 1 to the principal Order (functions the costs of which are to be taken into account in fixing fees under the 1971 Act)—

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

"4. Functions of the Committee on Safety of Medicines(4) established under section 4 of the 1968 Act.";

(b) after paragraph 9 there shall be inserted the following paragraph—

<sup>(1) 1987</sup> c. 51. Seesection 102(2) for the meaning of "power to fix a fee", "fee" and "the appropriate authority".

<sup>(2) 1971</sup> c. 69. Section 1(1) has effect from 1.1.95 as applied by regulation 9(12) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144).

<sup>(</sup>**3**) S.I. 1989/684.

<sup>(4)</sup> SeeS.I. 1970/1257.

**"9A.** Functions of the Licensing Authority which are functions of theirs by virtue of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**5**) and the functions of any person appointed under Schedule 2 to those Regulations.";

(c) in paragraph 10(c) after the words "and orders made under it" there shall be inserted the words "and of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994".

Signed by authority of the Secretary of State for Health.

| <i>Tom Sackvill</i><br>Parliamentary Under Secretary of State<br>Department of Healt     | 17th March 1995 |
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| John Redwood<br>Secretary of State for Wale  | 17th March 1995 |
| Fraser of Carmylli<br>Miniser of State<br>The Scottish Office                            | 17th March 1995 |
| Sir Patrick Mayhev<br>Secretary of State for Northern Ireland                            | 21st March 1995 |
| Angela Browning<br>Parliamentary Secretary Minister of Agriculture<br>Fisheries and Food | 23rd March 1995 |

### **EXPLANATORY NOTE**

(This note is not part of the Order)

This Order amends the Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Order 1989 ("the 1989 Order") which prescribes the functions and matters which are to be taken into account in fixing fees under the Medicines Act 1971 ("the 1971 Act"). Those fees relate to applications for licences and certificates under Part II of the Medicines Act 1968, the variation, renewal or holding of such licences and inspections relating to them.

Article 2(a) of the Order substitutes a new paragraph for paragraph 4 of the 1989 Order to take account of the disestablishment of—

- (a) the Committee on Review of Medicines by the Medicines (Committee on the Review of Medicines) (Revocation) Order 1992 (S.I. 1992/606); and
- (b) the Committee on Dental and Surgical Materials by the Medicines (Committee on Dental and Surgical Materials) (Revocation) Order 1994 (S.I. 1994/3120).

Article 2(b) and (c) of this Order extends the 1989 Order so that, in fixing fees under the 1971 Act, account is taken of the functions of the licensing authority under the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144) and of persons appointed under Schedule 2 to those Regulations and of functions relating to the enforcement of those Regulations.