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STATUTORY INSTRUMENTS

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**1990 No. 2326**

**MEDICINES**

**The Medicines (Fees Relating to Medicinal Products  
for Human Use) Amendment (No. 2) Regulations 1990**

<i>Made</i>	- - - -	<i>26th November 1990</i>
<i>Laid before Parliament</i>		<i>27th November 1990</i>
<i>Coming into force</i>		
<i>except those of regulations 3 and 8 of regulations 3 and 8</i>		<i>18th December 1990</i>
<i>for the purposes of regulations 3 and 8</i>		<i>1st January 1991</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 upon them by section 1(1) of the Medicines Act 1971<sup>(1)</sup>, or, as the case may be, those conferred by the said provisions and now vested in them<sup>(2)</sup> 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<sup>(3)</sup>, hereby make the following Regulations:—

**Citation, interpretation and commencement**

**1.** These Regulations which may be cited as the Medicines (Fees Relating to Medicinal Products for Human Use) Amendment (No. 2) Regulations 1990, amend the Medicines (Fees Relating to

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- (1) 1971 c. 69, as amended by section 21 of the Health and Medicines Act 1988 (c. 49); by virtue of section 1(3) of the 1971 Act expressions in that section have the same meaning as in the Medicines Act 1968 (c. 67), as amended by the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388). The expression “the Ministers” is defined in section 1(1) of the 1968 Act as so amended.
- (2) 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; 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); 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).
- (3) See section 129(6) of the Medicines Act 1968 (c. 67), as extended to include regulations made under the Medicines Act 1971 by section 1(3)(b) of that latter Act.

Medicinal Products for Human Use) Regulations 1989(4) (hereinafter referred to as “the principal Regulations”) and shall come into force for all purposes except those of regulations 3 and 8 on 18th December 1990 and for the purposes of regulations 3 and 8 on 1st January 1991.

### **Amendment of principal Regulations**

2. For each amount specified in column (3) of the Schedule to these Regulations, where it appears in the provision of the principal Regulations specified in relation to it in column (1) of that Schedule (the subject matter of which is indicated in column (2) of that Schedule), there is substituted the amount specified in relation to it in column (4) of that Schedule.

### **Revocation of regulation 1(3) of the principal Regulations**

3. Regulation 1(3) of the principal Regulations (exemption for National Health Service authorities) is hereby revoked.

### **Amendment of Part I of Schedule 1 to the principal Regulations**

4. In Schedule 1 to the principal Regulations (fees for applications, variations and renewals of licences), in paragraph 1 in Part I (interpretation), after the definition of “product licence (parallel import)”, there shall be inserted the following—

““qualified person” means the person named in the licence as being the person who is to carry out the functions specified in paragraph 16(3) of Schedule 2 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(5) in relation to a manufacturer’s licence or paragraph 8 of Schedule 3 to those Regulations in relation to a wholesale dealer’s licence;”.

### **Amendment of Part III of Schedule 1 to the principal Regulations**

5.—(1) In paragraph 2 of Part III of Schedule 1 to the principal Regulations (variations of manufacturers’ licences), for the words “paragraph 4” there shall be substituted the words “paragraphs 4A and 5”.

(2) In paragraph 3 of Part III of Schedule 1 to the principal Regulations (variations of wholesale dealers’ licences), for the words “paragraph 4” there shall be substituted the words “paragraphs 4B and 5”.

(3) For paragraph 4 of Part III of Schedule 1 to the principal Regulations (fees for applications for variations of licences) there shall be substituted the following—

#### **“Other variations to Product Licences**

4. The fee payable under regulation 6(a) of these Regulations in connection with an application for variation of a product licence shall be £100 in respect of each variation applied for which falls within one of the following paragraphs—

- (a) a change of either or both of the name and the address of the holder of the licence;
- (b) a change of either or both of the name and the address of a manufacturer, assembler, storer or distributor named in the licence where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise and any change of address does not involve a change of the site of manufacture, assembly or storage or from which distribution takes place;

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(4) S.I. 1989/418; the relevant amending instrument is S.I. 1990/210.

(5) S.I. 1971/972; the relevant amending instruments are S.I. 1972/1226 and 1977/1053.

- (c) the removal from the licence of details of one or more sites of manufacture, assembly or storage or from which distribution takes place;
- (d) the removal from the licence of details of any of the activities to which the licence relates;
- (e) the removal from the licence of details of any of the indications authorised for administration of the medicinal product;
- (f) in relation to a product licence (parallel import), the removal from the licence of details of any of the medicinal products which the holder of the licence is authorised to import.

#### **Other variations to Manufacturers' Licences**

**4A.** The fee payable under regulation 6(a) of these Regulations in connection with an application for variation of a manufacturer's licence shall be £100 in respect of each variation applied for which falls within one of the following paragraphs—

- (a) a change of either or both of the name and the address of the holder of the licence where any change of address does not involve a change of the site of manufacture, assembly or storage or from which distribution takes place;
- (b) a change of either or both of the name and the address of an assembler, storer or distributor named in the licence where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise, and any change of address does not involve a change of the site of manufacture, assembly or storage or from which distribution takes place;
- (c) the removal from the licence of details of one or more sites of manufacture, assembly or storage or from which distribution takes place;
- (d) the removal from the licence of details of one or more persons named as a qualified person, as the person to be in charge of quality control or as the production manager;
- (e) the removal from the licence of details of a medicinal product or range of medicinal products which the holder of the licence is authorised to manufacture;
- (f) the removal from the licence of details of one or more manufacturing or assembly operations specified in the licence as an operation which the holder of the licence is authorised to carry out.

#### **Other variations to Wholesale Dealers' Licences**

**4B.** The fee payable under regulation 6(a) of these Regulations in connection with an application for variation of a wholesale dealer's licence shall be £100 in respect of each variation applied for which falls within one of the following paragraphs—

- (a) a change of either or both of the name and the address of the holder of the licence where any change of address does not involve a change of the site of wholesale dealing or storage or from which distribution takes place;
- (b) a change of either or both of the name and the address of a storer or distributor named in the licence where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise and any change of address does not involve a change of the site of wholesale dealing or storage or from which distribution takes place;
- (c) the removal from the licence of details of one or more sites of wholesale dealing or storage or from which distribution takes place;

- (d) the removal from the licence of details of one or more persons named as a qualified person;
- (e) the removal from the licence of details of any medicinal product or range of medicinal products which the holder of the licence is authorised to sell or offer for sale by way of wholesale dealing.”.

### **Amendment of Schedule 2 to the principal Regulations**

6. In Schedule 2 to the principal Regulations (fees for inspections)—
- (a) in paragraph 1(1)—
    - (i) in the definition of “major inspection”, after the words “60 or more” there shall be inserted the words “, but fewer than 250,”;
    - (ii) after the definition of “standard inspection”, there shall be inserted the following sub-paragraph—
 

““supersite inspection” means an inspection at a site at which 250 or more relevant persons are employed.”;
  - (b) in paragraph 2—
    - (i) after sub-paragraph (a)(iii), there shall be inserted the following—
 

“(iv) in respect of a supersite inspection, £10,200.”;
    - (ii) after sub-paragraph (b)(iii), there shall be inserted the following—
 

“(iv) in respect of a supersite inspection, £17,000.”;
    - (iii) after sub-paragraph (c)(iii), there shall be inserted the following—
 

“(iv) in respect of a supersite inspection, £6,800.”.

### **Amendment of Schedule 3 to the principal Regulations**

7. In paragraph 3 of Schedule 3 to the principal Regulations (waiver, reduction or refund of fees) —
- (a) after the words “wholesale dealer’s licence” there shall be inserted the words “or for a variation or for a renewal of a manufacturer’s or a wholesale dealer’s licence”; and
  - (b) for the words “regulation 3(a)” there shall be substituted the words “regulations 3(a), 6 or 10”.

### **Transitional Provision**

8. Notwithstanding regulation 15(1) of the principal Regulations, where an application for the grant, variation or renewal of a licence or certificate under Part II of the Medicines Act 1968<sup>(6)</sup> is made before 1st April 1991 by an authority constituted under the National Health Service Act 1977<sup>(7)</sup>, the National Health Service (Scotland) Act<sup>(8)</sup> or by a National Health Service trust<sup>(9)</sup>, the fee payable in accordance with the other provisions of the principal Regulations in connection with the application shall be payable on 1st April 1991 and not at the time of the application.

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<sup>(6)</sup> 1968 c. 67.

<sup>(7)</sup> 1977 c. 49.

<sup>(8)</sup> 1978 c. 29.

<sup>(9)</sup> As established by orders made under section 5(1) of the National Health Service and Community Care Act 1990 (c. 19).

22nd November 1990

*William Waldegrave*  
Secretary of State for Health

Signed by authority of the Secretary of State for Wales

22nd November 1990

*Ian Grist*  
Parliamentary Under-Secretary of State, Welsh  
Office

22nd November 1990

*Malcolm Rifkind*  
Secretary of State for Scotland

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 22nd November 1990.

L.S.

*Trumpington*  
Minister of State, Ministry of Agriculture,  
Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 22nd November 1990.

L.S.

*D. C. Gowdy*  
Acting Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 22nd November 1990.

L.S.

*W. J. Hodges*  
Permanent Secretary

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**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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We consent,

26th November 1990

*John Taylor*  
*Sydney Chapman*  
Two of the Lords Commissioners of Her  
Majesty's Treasury

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## SCHEDULE

Regulation 2

Column (1) Provision in the principal Regulations	Column (2) Subject matter	Column (3) Old amount	Column (4) New amount
Regulation 4—	applications for clinical trial certificates	£13,600	£20,000
Regulation 7—	variations of clinical trial certificates	£300	£350
Regulation 8—	change of name and address in clinical certificates	£85	£100
Regulation 11—	renewal of certificates	£3,400	£5,000
Schedule 1—			
Part II—	fees for applications for licences		
Column 2 of the Table to paragraph 1—			
entry 1(a)		£13,600	£20,000
entry 1(b)		£68,000	£130,000
entry 2		£10,200	£20,000
entry 3		£5,100	£10,000
entry 4		£2,550	£3,000
entry 5(a)		£2,550	£3,000
entry 5(b)		£1,700	£2,000
paragraph 4(1)(a)		£85	£100
paragraph 4(1)(b)		£1,700	£1,955
Part III—	fees for applications for variations of licences		
paragraph 1(a)		£2,125	£2,000
paragraph 1(b)		£300	£350
paragraph 2(a)		£85	£100
Part IV—	fees for applications for renewals of licences		
paragraph 1(b)		£850	£800
paragraph 1(c)		£1,275	£1,200
paragraph 1(d)		£850	£800

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Column (1) Provision in the principal Regulations	Column (2) Subject matter	Column (3) Old amount	Column (4) New amount
paragraph 2(a)		£85	£100
paragraph 2(b)		£850	£1,000
Schedule 2—	fees for inspections		
paragraph 2(a)(i)		£1,275	£1,700
paragraph 2(a)(ii)		£2,550	£3,400
paragraph 2(b)(i)		£2,125	£2,750
paragraph 2(b)(ii)		£4,250	£5,500
paragraph 2(d)		£85	£100

## EXPLANATORY NOTE

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

These Regulations amend the Medicines (Fees Relating to Medicinal Products for Human Use) Regulations 1989 which prescribe fees in connection with applications and inspections relating to licences and certificates granted under the Medicines Act 1968 so far as they apply to medicinal products for human use only and insert a transitional provision in respect of applications made by specified health authorities (regulation 8).

These regulations (regulation 2 and the Schedule) vary the fees payable for applications for the grant of product licences, manufacturers' licences, clinical trial certificates and export certificates, for variations of such licences or certificates and for their renewal. They also increase some of the fees payable in respect of inspections of sites carried out in connection with applications for, or during the currency of, such licences or certificates.

The regulations revoke the exemption from paying fees in respect of health authorities constituted for any part of the United Kingdom (regulation 3).

These regulations make various other amendments as follows:—

- they insert a definition of qualified person (regulation 4) and widen the categories of variations of licences for which a reduced fee is payable (regulation 5);
- they add a new category of inspection for the purpose of calculating fees (regulation 6);
- they extend the provisions on waiver of fees (regulation 7).