STATUTORY INSTRUMENTS

1999 No. 566

MEDICINES
FEES AND CHARGES

The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1999

Made - - - -	*5th March 1999*
Laid before Parliament	*8th March 1999*
Coming into force - -	*1st April 1999*

The Secretary of State and the Department of Health and Social Services in Northern Ireland, being a Minister and a government department designated for the purposes of section 2(2) of the European Communities Act 1972(**1**) in relation to medicinal products(**2**), in exercise of the powers conferred upon them by the said section 2(2), the Secretary of State, with the consent of the Treasury, in exercise of the powers conferred upon him by section 56(1) and (2) of the Finance Act 1973(**3**), the Secretary of State concerned with health in England, the Minister of Agriculture, Fisheries and Food, the Secretaries of State concerned with health and agriculture in Wales and Scotland respectively, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly and with the consent of the Treasury, in exercise of powers conferred upon them by section 1(1) and (2) of the Medicines Act 1971(**4**), or, as the case may be, powers conferred by those provisions and now vested in them(**5**), and in each case in exercise of all other powers respectively enabling them in that behalf, after consultation in accordance with section 129(6) of the Medicines Act 1968(**6**), as extended by section 1(3)(b) of the Medicines Act 1971, with such organisations as appear to them to be representative of interests likely to be substantially affected, hereby make the following Regulations:–

(**1**) 1972 c. 68.
(**2**) S.I.1972/1811.
(**3**) 1973 c. 51.
(**4**) 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 used 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): *see* therefore section 1(1) of the 1968 Act, as so amended, which contains a definition of "the Ministers" which is relevant to the powers being exercised in the making of these Regulations. *See also* regulation 9(12) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144), by virtue of which the references in section 1(1) and (2)(b) of the 1971 Act to a licence under Part II of the 1968 Act include reference to a marketing authorization under those Regulations.
(**5**) 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).
(**6**) 1968 c. 67.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1999 and shall come into force on 1st April 1999.

(2) In these Regulations–

"the General Fees Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995(**7**);

"the Homoeopathic Products Regulations" means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**8**).

Amendment of the Homoeopathic Products Regulations

2.—(1) In regulation 14 of the Homoeopathic Products Regulations(**9**) (fees for variations of certificates)–

(a) in paragraph (1)(a), for "£75" there shall be substituted "£80";

(b) in paragraph (1)(b)(i), for "£75" there shall be substituted "£80";

(c) in paragraph (1)(b)(ii), for "£37.50" there shall be substituted "£40";

(d) in paragraph (2)(a), for "£150" there shall be substituted "£155";

(e) in paragraph (2)(b)(i), for "£150" there shall be substituted "£155"; and

(f) in paragraph (2)(b), for heads (ii) and (iii) there shall be substituted the following heads–

"(ii) in respect of each other application so considered, where further medical, technical or scientific assessment is required, a fee of £155,

(iii) in respect of the second to thirtieth applications so considered, where no further medical, technical or scientific assessment is required, a fee of £77.50, and

(iv) in respect of each other application so considered, where no further medical, technical or scientific assessment is required, a fee of £38.75.".

(2) In the Table in Schedule 2 to the Homoeopathic Products Regulations (fees for applications for the grant of certificates of registration)–

(a) in column (2) (fees for applications in respect of products prepared from not more than 5 homoeopathic stocks)–

(i) for "£90" there shall be substituted "£95",

(ii) for "£270" there shall be substituted "£285", and

(iii) for "£450" there shall be substituted "£470"; and

(b) in column (3) (fees for other applications)–

(i) for "£225" there shall be substituted "£235",

(ii) for "£400" there shall be substituted "£420", and

(iii) for "£585" there shall be substituted "£615".

(**7**) S.I. 1995/1116; amended by S.I. 1996/683 and 1998/574.
(**8**) S.I. 1994/105; amended by S.I. 1995/541, 1996/482 and 1998/574.
(**9**) *See* regulation 2(3) of S.I. 1998/574.

Amendment of regulation 3 of the Medical Devices (Consultation Requirements) (Fees) Regulations 1995

3. In regulation 3 of the Medical Devices (Consultation Requirements) (Fees) Regulations 1995(**10**) (fees)–

(a) in paragraph (1)(a), for "£1,910" there shall be substituted "£2,005";

(b) in paragraph (1)(b), for "£5,355" there shall be substituted "£5,620";

(c) in paragraph (2)(a), for "£475" there shall be substituted "£500";

(d) in paragraph (2)(b), for "£1,335" there shall be substituted "£1,400";

(e) in paragraph (3)(a), for "£1,910" there shall be substituted "£2,005";

(f) in paragraph (3)(b), for "£5,355" there shall be substituted "£5,620";

(g) in paragraph (4)(a), for "£475" there shall be substituted "£500";

(h) in paragraph (4)(b), for "£1,335" there shall be substituted "£1,400";

(i) in paragraph (5)(a), for "£24,500" there shall be substituted "£25,725"; and

(j) in paragraph (5)(b), for "£6,120" there shall be substituted "£6,425".

Amendment of the General Fees Regulations

4.—(1) In paragraph 6(a) of Part III of Schedule 1 to the General Fees Regulations (capital fees for applications for, and variations to, marketing authorizations, licences and certificates—fees payable in connection with an application for variation of a marketing authorization (parallel import)), after head (vi)(**11**) there shall be inserted the following head–

"(vii) subject to paragraph 6(b) of Schedule 5, a change consequential upon any or any combination of the following–

(aa) a change of ownership of the United Kingdom marketing authorization in respect of which the marketing authorization (parallel import) was granted,

(bb) a change to the number of the United Kingdom marketing authorization in respect of which the marketing authorization (parallel import) was granted,

(cc) a change to the name of the holder of the United Kingdom marketing authorization in respect of which the marketing authorization (parallel import) was granted,

(dd) a change to the address of the holder of the United Kingdom marketing authorization in respect of which the marketing authorization (parallel import) was granted,

(ee) a change of ownership of the marketing authorization for the product in the country where the product originates,

(ff) a change to the number of the marketing authorization for the product in the country where the product originates,

(gg) a change to the name of the holder of the marketing authorization for the product in the country where the product originates,

(hh) a change to the address of the holder of the marketing authorization for the product in the country where the product originates,

where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise,".

(**10**) S.I. 1995/449; the relevant amending instrument is S.I. 1998/574.
(**11**) Inserted by regulation 5(4) of S.I. 1996/683.

(2) In each provision of the General Fees Regulations specified in the entries in column (1) (the content of which is described in column (2)) of the Schedule to these Regulations, for the amount specified opposite that provision in column (3) of that Schedule there shall be substituted the amount specified opposite that provision in column (4) of that Schedule.

Revocation

5. Regulation 2(5) and 3 of the Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1998(**12**) are hereby revoked.

Signed by authority of the Secretary of State for Health

Hayman
Parliamentary Under Secretary of State,
25th February 1999 Department of Health

Signed by authority of the Secretary of State for Wales

Jon Owen Jones
Parliamentary Under Secretary of State, Welsh
5th March 1999 Office

Sam Galbraith
Parliamentary Under Secretary of State, Scottish
25th February 1999 Office

Jeff Rooker
Minister of State, Ministry of Agriculture,
25th February 1999 Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on

L.S.

D.C. Gowdy
1st March 1999. Permanent Secretary

(**12**) S.I. 1998/574.

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on

L.S.

P. Small
24th February 1999. Permanent Secretary

We consent,

Bob Ainsworth
Jim Dowd
Two of the Lords Commissioners of Her
3rd March 1999 Majesty's Treasury

SCHEDULE Regulation 4(2)

Column (1) Provision in the General Regulations	*Column (2)* Subject matter	*Column (3)* Old amount	*Column (4)* New amount
Regulation 6	Applications for certificates by exporters of medicinal products		
Regulation 6(1)(a)		£80	£85
Regulation 6(1)(c)(ii)		£14	£15
Regulation 10	Renewals of clinical trial certificates	£1,500	£1,575
Regulation 11(1)	Renewals of certain manufacturers' licences	£85	£90
Part II of Schedule 1	Capital fees for applications for authorizations, licences and certificates		
In column 2 of the table in paragraph 1(1)			
Entry 1(a)		£18,000	£18,900
Entry 1(b)		£38,500	£40,425
Entry 1(c)		£55,000	£57,750
Entry 2(a)		£10,500	£11,025
Entry 2(b)		£15,000	£15,750
Entry 3(a)		£3,850	£4,040
Entry 3(b)		£5,500	£5,775
Entry 4		£1,500	£1,575
Entry 5		£1,000	£1,050
Entry 6		£250	£260
Paragraph 5(1)(a)		£95	£100
Paragraph 5(1)(b)		£180	£190
Paragraph 5(1)(c)		£1,650	£1,730
Paragraph 6(1)		£650	£680
Paragraph 6(2)		£475	£500
Paragraph 6(4)		£210	£220
Paragraph 7		£11,600	£12,180

Column (1) Provision in the General Regulations	*Column (2)* Subject matter	*Column (3)* Old amount	*Column (4)* New amount
Part III of Schedule 1	Capital fees for applications for variations of authorizations, licences and certificates		
Paragraph 2(a)		£150	£155
Paragraph 2(b)		£340	£355
Paragraph 2(c)		£5,000	£5,250
Paragraph 3(a)		£230	£240
Paragraph 3(b)		£410	£430
Paragraph 3(c)		£7,800	£8,190
Paragraph 6(a)		£95	£100
Paragraph 6(b)		£200	£210
Paragraph 7(a)		£90	£95
Paragraph 7(b)		£180	£190
Paragraph 8		£90	£95
Paragraph 9		£210	£220
Paragraph 10		£90	£95
Paragraph 11		£150	£155
Paragraph 12		£75	£80
Schedule 2	Fees for inspections		
Paragraph 2(a)(i)		£1,560	£1,640
Paragraph 2(a)(ii)		£2,900	£3,045
Paragraph 2(a)(iii)		£3,500	£3,675
Paragraph 2(a)(iv)		£6,000	£6,300
Paragraph 2(b)(i)		£1,700	£1,785
Paragraph 2(b)(ii)		£3,500	£3,675
Paragraph 2(b)(iii)		£5,500	£5,775
Paragraph 2(b)(iv)		£10,000	£10,500
Paragraph 2(c)(i)		£600	£630
Paragraph 2(c)(ii)		£1,680	£1,764
Paragraph 2(c)(iii)		£2,510	£2,635
Paragraph 2(c)(iv)		£4,700	£4,935
Paragraph 2(d)		£115	£120

Column (1) Provision in the General Regulations	*Column (2)* Subject matter	*Column (3)* Old amount	*Column (4)* New amount
Paragraph 5(1)		£315	£330
Paragraph 5(1)		£690	£725
Part III of Schedule 3	Periodic fees for marketing authorizations and licences		
In column 2 of the table in paragraph 1			
Entry 1		£10,200	£10,710
Entry 2(a)		£4,000	£4,200
Entry 2(b)(i)		£1,000	£1,050
Entry 2(b)(ii)		£500	£525
Entry 2(b)(iii)		£165	£170
Entry 2(c)(i)		£440	£460
Entry 2(c)(ii)		£220	£230
Entry 2(c)(iii)		£80	£85
Entry 2(d)(i)		£180	£190
Entry 2(d)(ii)		£90	£95
Entry 2(d)(iii)		£40	£42
Entry 2(e)		£50	£52
Paragraph 2(a)		£225	£235
Paragraph 2(b)		£110	£115
Paragraph 2(c)		£45	£48
Paragraph 3(a)		£4,000	£4,200
Paragraph 3(b)		£2,700	£2,835
Paragraph 7		£200	£210
Paragraph 8(1)		£125	£130
Paragraph 8(2)		£75	£78

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 ("the Homoeopathic Products Regulations"), the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 ("the Consultation Requirements Regulations") and the Medicines (Products for Human Use—Fees) Regulations 1995 ("the General Fees Regulations").

The Homoeopathic Products Regulations implemented in part Council Directive 92/73/EEC(**13**) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for human use. Regulation 2 of these Regulations makes further amendments to the Homoeopathic Products Regulations: introducing further discounts in respect of the fees payable for multiple identical applications for standard variations of certificates of registration by providing for a reduction of 75% in certain cases; and otherwise increasing the level of the capital fees payable in respect of applications for the grant of certificates of registration and for variations by an average overall of 5%.

The Consultation Requirements Regulations prescribe the fees which are payable where a notified body consults the competent body in accordance with Council Directive 93/42/EEC(**14**) concerning medical devices. Regulation 3 of these Regulations amends regulation 3 of the Consultation Requirements Regulations by increasing the amounts of all the fees specified in those Regulations by an average overall of 5%.

The General Fees Regulations make provision for the fees payable under the Medicines Act 1971 relating to marketing authorizations, licences and certificates in respect of medicinal products for human use. Regulation 4(1) of these Regulations amends Part III of Schedule 1 to the General Fees Regulations in order to widen the category of applications for variations of marketing authorizations (parallel import) which attract the lower level fee. There is also a package of changes relating to the levels of: the capital fees payable for applications for marketing authorizations, manufacturers' licences, wholesale dealers' licences, clinical trial certificates and export certificates; capital fees for variations and renewals of such authorizations, licences and certificates; periodic fees payable in connection with the holding of certain authorizations and licences; and fees payable in connection with site inspections (regulation 4(2) and the Schedule). Fees have been increased by an average overall of 5%.

Regulation 5 revokes two provisions which are spent as a result of the coming into force of these Regulations.

A Regulatory Impact Appraisal in relation to these Regulations has been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines Control Agency, Room 2102, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

(**13**) OJ No. L 297, 13.10.92, p.8.
(**14**) OJ No. L 169, 12.7.93, p.1.