STATUTORY INSTRUMENTS

1998 No. 574

MEDICINES FEES AND CHARGES

The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1998

Made - - - -	*5th March 1998*
Laid before Parliament	*11th March 1998*
Coming into force - -	*1st April 1998*

The Secretary of State concerned with health in England, the Secretaries of State concerned with health and agriculture in Wales and Scotland respectively, 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 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(**1**), or, as the case may be, powers conferred by those provisions and now vested in them(**2**), the Secretary of State, being a Minister designated for the purposes of section 2(2) of the European Communities Act 1972(**3**) in relation to medicinal products(**4**), in exercise of the powers conferred upon him by the said section 2(2), and 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(**5**), and in each case in exercise of all other powers respectively enabling them in that behalf, after consultation (in so far as is required by 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**) 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.

(**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**) 1972 c. 68.

(**4**) S.I. 1972/1811.

(**5**) 1973 c. 51.

(**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 1998 and shall come into force on 1st April 1998.

(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 1(2) of the Homoeopathic Products Regulations (interpretation)—

(a) after the definition of "the Act" there shall be inserted the following definition—

""administrative variation" means a variation of the provisions of a certificate of registration which does not require, in the opinion of the licensing authority, medical, scientific or pharmaceutical assessment;"; and

(b) after the definition of "homoeopathic medicinal product" there shall be inserted the following definition—

""standard variation" means a variation of the provisions of a certificate of registration which, in the opinion of the licensing authority, requires medical, scientific or pharmaceutical assessment and which requires in respect of any homoeopathic medicinal product to which that certificate relates—

(a) the replacement of an excipient used in the manufacture of the product with a comparable excipient;

(b) the replacement of a reagent indirectly associated with the manufacturing process of the product or which disappears from that process with a comparable reagent;

(c) a change to the qualitative composition of the container or other form of packaging immediately in contact with the product;

(d) a minor change to the method of manufacture of a homoeopathic stock included in the product;

(e) a change to the specification of any reagent or excipient used in the manufacture of the product;

(f) a change to the finished product specification of the product;

(g) a change to the test procedure for any raw material used in the manufacture of the product;

(h) a change to the test procedure for the product;

(i) a change to the test procedure for the container or other form of packaging immediately in contact with the product;

(j) a change to comply with a supplement to the European Pharmacopoeia or any national pharmacopoeia of a member State;

(k) a change to the shape of the container in which the product may be placed on the market;

(**7**) S.I. 1995/1116; amended by S.I. 1996/683.
(**8**) S.I. 1994/105; amended by S.I. 1995/541 and 1996/482.

(l) an additional pack size in which the product may be placed on the market;

(m) a change to the approved storage conditions for the product;

(n) a change to the shelf life of an unopened container of the product or to the shelf life of the product after the container has been opened for the first time; or

(o) a change to the dimensions of an approved dosage form of the product (for example, tablets) which does not entail a change to the quantitative composition or the mean mass of the product;".

(2) In regulation 11 of the Homoeopathic Products Regulations (variation of certificates)—

(a) after the words "certificate of registration" there shall be inserted the words "for an administrative variation or a standard variation"; and

(b) the words from "which relate to" to the end of the regulation shall be omitted.

(3) For regulation 14 of the Homoeopathic Products Regulations (fees for variations of certificates) there shall be substituted the following regulation—

"**Fees for variations of certificates**

14.—(1) The fee payable by an applicant in connection with an application for an administrative variation of a certificate of registration pursuant to regulation 11 of these Regulations shall be—

(a) unless sub-paragraph (b) applies, a fee of £75;

(b) where more than one application for an administrative variation is made at the same time by the same applicant and the applications are for identical variations—

(i) in respect of the first application considered by the licensing authority, a fee of £75, and

(ii) in respect of each other application so considered, a fee of £37.50.

(2) The fee payable by an applicant in connection with an application for a standard variation of a certificate of registration pursuant to regulation 11 of these Regulations shall be—

(a) unless sub-paragraph (b) applies, a fee of £150;

(b) where more than one application for a standard variation is made at the same time by the same applicant and the applications are for identical variations—

(i) in respect of the first application considered by the licensing authority, a fee of £150, and

(ii) in respect of each other application so considered, where further medical, technical or scientific assessment is required, a fee of £150,

(iii) in respect of each other application so considered, where no further medical, technical or scientific assessment is required, a fee of £75.".

(4) In regulation 15(1) of the Homoeopathic Products Regulations (fees payable by holders of certificates), for "£15" there shall be substituted "£10".

(5) 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 "£100" there shall be substituted "£90",

(ii) for "£300" there shall be substituted "£270", and

(iii) for "£500" there shall be substituted "£450"; and

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

(i) for "£250" there shall be substituted "£225",

(ii) for "£450" there shall be substituted "£400", and

(iii) for "£650" there shall be substituted "£585".

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(**9**) (fees)—

(a) in paragraph (1)(a), for "£2,125" there shall be substituted "£1,910";

(b) in paragraph (1)(b), for "£5,950" there shall be substituted "£5,355";

(c) in paragraph (2)(a), for "£530" there shall be substituted "£475";

(d) in paragraph (2)(b), for "£1,485" there shall be substituted "£1,335";

(e) in paragraph (3)(a), for "£2,125" there shall be substituted "£1,910";

(f) in paragraph (3)(b), for "£5,950" there shall be substituted "£5,355";

(g) in paragraph (4)(a), for "£530" there shall be substituted "£475";

(h) in paragraph (4)(b), for "£1,485" there shall be substituted "£1,335";

(i) in paragraph (5)(a), for "£27,200" there shall be substituted "£24,500"; and

(j) in paragraph (5)(b), for "£6,800" there shall be substituted "£6,120".

Amendment of the General Fees Regulations

4.—(1) In the following provisions of the General Fees Regulations—

(a) paragraph 6(2)(b) of Part II of Schedule 1;

(b) paragraph 5(2)(c) of Schedule 2;

(c) the definitions of "reduced rate fee" and "standard fee" in paragraph 1 of Part I of Schedule 3; and

(d) paragraph 8(2)(a) of Part III of Schedule 3,

for "£30,000" there shall be substituted "£35,000".

(2) In paragraph 1 of Part III of Schedule 1 to the General Fees Regulations (capital fees for applications for variations to marketing authorizations, licences and certificates—marketing authorizations)—

(a) in the definition of "Type II Application", for the words "an application for a Type II complex variation" there shall be substituted the words "a Type II Complex Variation Application";

(b) for the words ""Type II complex variation" means" there shall be substituted the words ""Type II Complex Variation Application" means an application for"; and

(c) for sub-paragraph (b) of what, by virtue of the preceding sub-paragraph, is the definition of "Type II Complex Variation Application" there shall be substituted the following sub-paragraph—

(**9**) S.I. 1995/449; amended by S.I. 1996/622.

"(b) which is considered a "major variation" within the meaning given in article 3.1(b) of Commission Regulation (EC) No. 541/95(**10**) and which is—

(i) supported by data which comprises or includes the results of clinical trials or physico-chemical, biological, microbiological or pharmacological and toxicological tests, or

(ii) accompanied by evidence relating to post-marketing experience which is information of any type described in Section H of Part IV of the Annex to Council Directive 75/318/EEC(**11**) (clinical documentation); or".

(3) In paragraphs 2(c) and 3(c) of Part III of Schedule 1 to the General Fees Regulations, for the words "complex variation", at each place where they occur, there shall be substituted the words "Complex Variation Application".

(4) In paragraph 14 of Part III of Schedule 1 to the General Fees Regulations, for the words "application for a Type II complex variation" there shall be substituted the words "Type II Complex Variation Application".

(5) In paragraph 1(1) of Part II of Schedule 3 to the General Fees Regulations (periodic fees for licences—calculation of turnover), for the words "year which ends on the 31st December preceding the beginning of that" there shall be substituted the words "period of 12 months preceding the commencement of the relevant".

(6) In the table in paragraph 1 of Part III of Schedule 3 to the General Fees Regulations (periodic fees for licences—marketing authorizations), entry 2(f) in column 1 and entry 2(f) in column 2 shall be omitted.

Changes to fees in the General Fees Regulations

5. 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

6. The Medical Devices (Consultation Requirements) (Fees) Amendment Regulations 1996(**12**) are hereby revoked.

Signed by authority of the Secretary of State for Health

Jay
Minister of State
Department of Health

24th February 1998

(**10**) OJ No. L 55, 11.3.95, p. 7.
(**11**) OJ No. L 147, 9.6.75, p. 1; amended by Council Directive 83/570/EEC (OJ No. L 332, 28.11.83, p. 1), Council Directive 87/19/EEC (OJ No. L 15, 17.1.87, p. 31), Council Directive 89/341/EEC (OJ No. L 142, 25.5.89, p. 11), Commission Directive 91/507/EEC (OJ No. L 270, 26.9.91, p. 32) and Council Directive 93/39/EEC (OJ No. L 214, 24.8.93, p. 22).
(**12**) S.I. 1996/622.

Signed by authority of the Secretary of State for Wales

Win Griffiths
Parliamentary Under Secretary of State Welsh Office
27th February 1998

Sam Galbraith
Parliamentary Under Secretary of State Scottish Office
4th March 1998

Jeff Rooker
Minister of State Ministry of Agriculture Fisheries and Food
3rd March 1998

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

L.S.

Mr D. C. Gowdy
Permanent Secretary
27th February 1998.

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

L.S.

P. J. Small
Permanent Secretary
3rd March 1998.

We consent,

Graham Allen
Bob Ainsworth
Two of the Lords Commissioners of Her Majesty's Treasury
5th March 1998

SCHEDULE Regulation 5

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)		£110	£80
Regulation 6(1)(b)		£55	£30
Regulation 6(1)(c)(i)		£55	£30
Regulation 10	Renewals of clinical trial certificates	£1,925	£1,500
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)		£20,165	£18,000
Entry 1(b)		£50,365	£38,500
Entry 1(c)		£71,950	£55,000
Entry 2(a)		£11,080	£10,500
Entry 2(b)		£15,830	£15,000
Entry 3(a)		£4,045	£3,850
Entry 3(b)		£5,775	£5,500
Entry 4		£1,710	£1,500
Entry 5		£1,490	£1,000
Entry 6		£750	£250
Paragraph 5(1)(c)		£1,690	£1,650
Paragraph 6(1)		£780	£650
Part III of Schedule 1	Capital fees for applications for variations of authorizations, licences and certificates		
Paragraph 2(a)		£190	£150
Paragraph 2(b)		£342	£340

Column (1) *Provision in the General Regulations*	*Column (2)* *Subject matter*	*Column (3)* *Old amount*	*Column (4)* *New amount*
Paragraph 2(c)		£8,766	£5,000
Paragraph 3(c)		£10,520	£7,800
Paragraph 6(b)		£310	£200
Paragraph 11		£195	£150
Schedule 2	Fees for inspections		
Paragraph 2(a)(ii)		£2,945	£2,900
Paragraph 2(a)(iii)		£4,750	£3,500
Paragraph 2(a)(iv)		£8,125	£6,000
Paragraph 2(b)(i)		£1,740	£1,700
Paragraph 2(b)(ii)		£4,650	£3,500
Paragraph 2(b)(iii)		£7,100	£5,500
Paragraph 2(b)(iv)		£13,510	£10,000
Part III of Schedule 3	Periodic fees for marketing authorizations and licences		
In column 2 of the table in paragraph 1			
Entry 1		£11,300	£10,200
Entry 2(a)		£4,800	£4,000
Entry 2(b)(i)		£1,130	£1,000
Entry 2(b)(ii)		£560	£500
Entry 2(b)(iii)		£190	£165
Entry 2(c)(i)		£535	£440
Entry 2(c)(ii)		£270	£220
Entry 2(c)(iii)		£120	£80
Entry 2(d)(i)		£240	£180
Entry 2(d)(ii)		£120	£90
Entry 2(d)(iii)		£90	£40
Entry 2(e)		£60	£50
Paragraph 2(a)		£300	£225
Paragraph 2(b)		£145	£110
Paragraph 2(c)		£95	£45
Paragraph 3(a)		£4,800	£4,000

Column (1) *Provision in the General Regulations*	*Column (2)* *Subject matter*	*Column (3)* *Old amount*	*Column (4)* *New amount*
Paragraph 3(b)		£3,400	£2,700
Paragraph 7		£235	£200
Paragraph 8(1)		£145	£125
Paragraph 8(2)		£90	£75

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. These Regulations introduce a new category of permissible variation of certificates of registration, allowing for certificates to be varied in some circumstances where medical, scientific or pharmaceutical assessment is required (regulation 2(1) and (2)). The fee payable in respect of variations is £75 (for administrative) or £150 (for standard), reduced by half in respect of certain applications for identical variations (regulation 2(3)). The periodic fee payable by holders of certificates of registration is reduced from £15 to £10 (regulation 2(4)), and the capital fees for applications for the grant of certificates of registration are reduced by an average overall of 10% (regulation 2(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 concerning medical devices(**14**). Regulation 3 of these Regulations amends regulation 3 of the Consultation Requirements Regulations by reducing the amounts of all the fees specified in those Regulations by an average overall of 10%. As a consequence, the Medical Devices (Consultation Requirements) (Fees) Amendment Regulations 1996 are revoked (regulation 6).

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. These Regulations change the turnover threshold for reductions on certain of the fees for small businesses from £30,000 to £35,000 (regulation 4(1)). They also change the definition relating to major complex variation applications which applies for the purposes of Part III of Schedule 1 to the General Fees Regulations so that the higher major complex variation application fee is now generally payable in respect of applications which must include evidence relating to certain studies, tests or trials and which require substantial assessment resources on the part of the licensing authority (regulation 4(2) to (4)). Dates relating to the calculation of turnover for periodic fees' purposes are

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

made consistent with the dates relating to other calculations under Schedule 3 (regulation 4(5)), and a periodic fee will no longer be charged for homoeopathic product licences of right or for anthroposophic products (regulation 4(6)). There is also a package of changes relating to the levels of certain capital fees payable for applications for marketing authorizations, manufacturers' licences, wholesale dealers' licences, clinical trial certificates and export certificates; 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 certain site inspections (regulation 5 and the Schedule). No fees have been increased. Most of the capital fees have been reduced, by amounts varying between 0.5% and 65%; periodic fees have been reduced by an average overall of 14%; and just under half of the fees for site inspections have been reduced, by amounts varying between 0.5% and 26%.

A Regulatory 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.