STATUTORY INSTRUMENTS

2000 No. 592

MEDICINES
FEES AND CHARGES

The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 2000

Made - - - -	*6th March 2000*
Laid before Parliament	*7th March 2000*
Coming into force - -	*1st April 2000*

The Secretary of State, being a Minister 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 him 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 Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, 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 article 2(2) of, and Schedule 1 to, S.I. 1969/388 and by article 5 of, and the Schedule to, S.I. 1999/3142; *see* therefore section 1(1) of the 1968 Act, 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 the 1994 Regulations.
(**5**) In the case of the Secretary of State concerned with health in England, by virtue of articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142; in the case of the Minister of Agriculture, Fisheries and Food, by virtue of articles 2(2) and 5 of, and the Schedule to, S.I. 1999/3142; in the case of the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, the powers vested in the Ministers in charge of those Departments by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47) may now be exercised by the Departments by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c. 1).
(**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 2000 and shall come into force on 1st April 2000.

(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 "£80" there shall be substituted " £90";

(b) in paragraph (1)(b)(i), for "£80" there shall be substituted " £90";

(c) in paragraph (1)(b)(ii), for "£40" there shall be substituted " £45";

(d) in paragraph (2)(a), for "£155" there shall be substituted " £176";

(e) in paragraph (2)(b)(i), for "£155" there shall be substituted " £176";

(f) in paragraph (2)(b)(ii), for "£155" there shall be substituted " £176";

(g) in paragraph (2)(b)(iii), for "£77.50" there shall be substituted " £88"; and

(h) in paragraph (2)(b)(iv), for "£38.75" there shall be substituted " £44".

(2) In regulation 15(1) of the Homoeopathic Products Regulations(**10**) (fee payable by holders of certificates), for "£10" there shall be substituted "£11".

(3) In the Table in Schedule 2 to the Homoeopathic Products Regulations(**11**) (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 "£95" there shall be substituted "£108",

(ii) for "£285" there shall be substituted "£325", and

(iii) for "£470" there shall be substituted "£535"; and

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

(i) for "£235" there shall be substituted "£267",

(ii) for "£420" there shall be substituted "£478", and

(iii) for "£615" there shall be substituted "£701".

(**7**) S.I. 1995/1116; amended by S.I. 1996/683, 1998/574 and 1999/566.
(**8**) S.I. 1994/105; amended by S.I. 1995/541, 1996/482, 1998/574 and 1999/566.
(**9**) As amended by regulation 2(3) of S.I. 1998/574 and regulation 2(1) of S.I. 1999/566.
(**10**) As amended by regulation 2(4) of S.I. 1998/574.
(**11**) As amended by regulation 2(2) of S.I. 1999/566.

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(**12**) (fees)–

(a) in paragraph (1)(a), for "£2,005" there shall be substituted " £2,285";

(b) in paragraph (1)(b), for "£5,620" there shall be substituted " £6,406";

(c) in paragraph (2)(a), for "£500" there shall be substituted " £570";

(d) in paragraph (2)(b), for "£1,400" there shall be substituted " £1,596";

(e) in paragraph (3)(a), for "£2,005" there shall be substituted " £2,285";

(f) in paragraph (3)(b), for "£5,620" there shall be substituted " £6,406";

(g) in paragraph (4)(a), for "£500" there shall be substituted " £570";

(h) in paragraph (4)(b), for "£1,400" there shall be substituted " £1,596";

(i) in paragraph (5)(a), for "£25,725" there shall be substituted " £29,326"; and

(j) in paragraph (5)(b), for "£6,425" there shall be substituted " £7,324".

Amendment of the General Fees Regulations

4.—(1) In paragraph (1) of regulation 2 of the General Fees Regulations(**13**) (interpretation), after the definition of "medicinal product" there shall be inserted the following definition–

> ""orphan medicinal product" has the meaning given in article 2(b) of Regulation (EC) No. 141/2000(**14**) of the European Parliament and of the Council of 16th December 1999 on orphan medicinal products;".

(2) In Column 1 of the Table set out in paragraph 1 of Part II of Schedule 1 to the General Fees Regulations (which contains a list of types of application for a marketing authorization in connection with which a capital fee is payable), for the words "any such application" in entry 1(a) there shall be substituted the words "any application relating to an orphan medicinal product or a product".

(3) In the following provisions–

(a) paragraphs 4 and 5 of Part III of Schedule 1 to the General Fees Regulations (which relate to the capital fee payable for the first application for a variation of a marketing authorization granted in respect of a limited use drug); and

(b) paragraph 1 of Part I of Schedule 3 to the General Fees Regulations(**16**) (interpretation of Schedule 3),

after the words "Directive 75/318/EEC(**15**) applies", at each place where they occur, there shall be inserted the words "or which is in respect of an orphan medicinal product".

(4) In paragraph 4 of Part III of Schedule 3 to the General Fees Regulations(**17**) (which relates to the periodic fees payable in connection with the holding of certain marketing authorizations)–

(a) before sub-paragraph (3) there shall be inserted the following sub-paragraph–

(**12**) S.I. 1995/449; as amended by regulation 3 of S.I. 1999/566.
(**13**) As amended by regulation 2 of S.I. 1996/683.
(**14**) O.J. No. L18, 22.1.2000, p.1.
(**16**) As amended by regulation 6(1) of S.I. 1996/683.
(**15**) O.J. No. L147, 9.6.1975, p.1. This Directive has been amended by Council Directive 95/319/EEC (O.J. No. L147, 9.6.1975, p.13), Council Directive 83/570/EEC (O.J. No. L332, 28.11.1983, p.1), Council Directive 87/19/EEC (O.J. No. L15, 17.1.1987, p.31), Council Directive 89/341/EEC (O.J. No. L142, 25.5.1989, p.11), Commission Directive 91/507/EEC (O.J. No. L270, 26.9.1991, p.32), Council Directive 93/39/EEC (O.J. No. L214, 24.8.93, p.22), Commission Directive 1999/82/EC (O.J. No. L243, 15.9.1999, p.7) and Commission Directive 1999/83/EC (O.J. No. L243, 15.9.1999, p.9).
(**17**) As amended by regulation 6(3) of S.I. 1996/683.

"(2A) The fee payable in respect of–

(a) a new active substance in accordance with entry 1 of the Table set out in paragraph 1; or

(b) a derivative of a new active substance in accordance with paragraph 3,

shall only be payable for the five relevant fee periods following the fee period during which the marketing authorization was granted.";

(b) in sub-paragraph (4)(a), for the words "each fee period mentioned in sub-paragraph (1)," there shall be substituted the words "the five relevant fee periods following the fee period during which the marketing authorization was granted,";

(c) in sub-paragraph (5), for the words "sub-paragraphs (1), (2) and (3) " there shall be substituted the words "sub-paragraphs (2A) to (4)"; and

(d) for sub-paragraph (6) there shall be substituted the following sub-paragraph–

"(6) In connection with the holding of a marketing authorization in respect of a limited use drug or a derivative of a limited use drug–

(a) where turnover exceeds £200,000, until the expiry of the five relevant fee periods following the fee period during which the marketing authorization was granted, the periodic fee payable shall be the fee that would be payable if the drug were, respectively, a new active substance or a derivative of a new active substance;

(b) where turnover does not exceed £200,000 or where a periodic fee has been payable in respect of the limited use drug or derivative of a limited use drug for five relevant fee periods following the fee period during which the marketing authorization was granted, the periodic fee payable shall be the fee payable in respect of a prescription only medicine in accordance with entry 2(b)(i) of the Table set out in paragraph 1.".

(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

5. Regulations 2(1)(a) to (e) and (2), 3 and 4(2) of Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1999(**18**) are hereby revoked.

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
Department of Health

1st March 2000

(**18**) S.I. 1999/566.

Hayman
Minister of State, Ministry of Agriculture,
6th March 2000 Fisheries and Food

D.C. Gowdy
Permanent Secretary,
Department of Health, Social Services and
6th March 2000 Public Safety

P. Small
Permanent Secretary,
Department of Agriculture and Rural
3rd March 2000 Development

We consent,

Bob Ainsworth
Greg Pope
Two of the Lords Commissioners of Her
6th March 2000 Majesty's Treasury

SCHEDULE Regulation 4(5)

Column (1) Provision in the General Fees Regulations	*Column (2)* Subject matter	*Column (3)* Old amount	*Column (4)* New amount
Regulation 6	Applications for certificates by exporters of medicinal products		
Paragraph (1)(a)		£85	£96
Paragraph (1)(b)		£30	£34
Paragraph (1)(c)(i)		£30	£34
Paragraph (1)(c)(ii)		£15	£17
Regulation 10	Renewals of clinical trial certificates	£1,575	£1,795
Regulation 11(1)	Renewals of certain manufacturer's licences	£90	£102
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)		£18,900	£21,545
Entry 1(b)		£40,425	£46,085
Entry 1(c)		£57,750	£65,835
Entry 2(a)		£11,025	£12,568
Entry 2(b)		£15,750	£17,955
Entry 3(a)		£4,040	£4,605
Entry 3(b)		£5,775	£6,584
Entry 4		£1,575	£1,795
Entry 5		£1,050	£1,196
Entry 6		£260	£296
Paragraph 5(1)(a)		£100	£114
Paragraph 5(1)(b)		£190	£216
Paragraph 5(1)(c)		£1,730	£1,972
Paragraph 6(1)		£680	£775

Column (1) Provision in the General Fees Regulations	*Column (2)* Subject matter	*Column (3)* Old amount	*Column (4)* New amount
Paragraph 6(2)		£500	£570
Paragraph 6(4)		£220	£250
Paragraph 7		£12,180	£13,885
Part III of Schedule 1	Capital fees for applications for variations of authorizations, licences and certificates		
Paragraph 2(a)		£155	£176
Paragraph 2(b)		£355	£404
Paragraph 2(c)		£5,250	£5,984
Paragraph 3(a)		£240	£274
Paragraph 3(b)		£430	£490
Paragraph 3(c)		£8,190	£9,336
Paragraph 6(a)		£100	£114
Paragraph 6(b)		£210	£239
Paragraph 7(a)		£95	£108
Paragraph 7(b)		£190	£216
Paragraph 8		£95	£108
Paragraph 9		£220	£250
Paragraph 10		£95	£108
Paragraph 11		£155	£176
Paragraph 12		£80	£90
Schedule 2	Fees for inspections		
Paragraph 2(a)(i)		£1,640	£1,870
Paragraph 2(a)(ii)		£3,045	£3,470
Paragraph 2(a)(iii)		£3,675	£4,190
Paragraph 2(a)(iv)		£6,300	£7,182
Paragraph 2(b)(i)		£1,785	£2,034
Paragraph 2(b)(ii)		£3,675	£4,190
Paragraph 2(b)(iii)		£5,775	£6,582
Paragraph 2(b)(iv)		£10,500	£11,970
Paragraph 2(c)(i)		£630	£718

Column (1) Provision in the General Fees Regulations	*Column (2)* Subject matter	*Column (3)* Old amount	*Column (4)* New amount
Paragraph 2(c)(ii)		£1,764	£2,010
Paragraph 2(c)(iii)		£2,635	£3,003
Paragraph 2(c)(iv)		£4,935	£5,625
Paragraph 2(d)		£120	£136
Paragraph 5(1)		£330	£376
Paragraph 5(1)		£725	£826
Part III of Schedule 3	Periodic fees for marketing authorizations and licences		
In column 2 of the Table in paragraph 1			
Entry 1		£10,710	£12,209
Entry 2(a)		£4,200	£4,788
Entry 2(b)(i)		£1,050	£1,197
Entry 2(b)(ii)		£525	£598
Entry 2(b)(iii)		£170	£194
Entry 2(c)(i)		£460	£524
Entry 2(c)(ii)		£230	£262
Entry 2(c)(iii)		£85	£97
Entry 2(d)(i)		£190	£216
Entry 2(d)(ii)		£95	£108
Entry 2(d)(iii)		£42	£48
Entry 2(e)		£52	£59
Paragraph 2(a)		£235	£268
Paragraph 2(b)		£115	£131
Paragraph 2(c)		£48	£55
Paragraph 3(a)		£4,200	£4,788
Paragraph 3(b)		£2,835	£3,232
Paragraph 7		£210	£239
Paragraph 8(1)		£130	£148
Paragraph 8(2)		£78	£89

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make further amendments to 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(**19**) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for human use. Regulation 2 of these Regulations amends the Homoeopathic Products Regulations by increasing the amounts of the capital fees payable for applications for certificates of registration and for variations of certificates of registration, and the amount of the periodic fee payable by holders of certificates of registration, by an average overall of 14%.

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(**20**) 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 14%.

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) to (3) of these Regulations contains amendments to provisions of the General Fees Regulations that relate to limited use drugs. These changes are consequential amendments relating to the new scheme for designating medicinal products as orphan medicinal products set out in Regulation (EC) No. 141/2000 of the European Parliament and of the Council. Regulation 4(4) of these Regulations amends paragraph 4 of Part III of Schedule 3 to the General Fees Regulations, limiting the occasions when a higher rate periodic fee is payable in connection with the holding of a marketing authorization in respect of a new active substance, a limited use drug or a derivative of such a substance or drug.

There is also a package of changes to the General Fees Regulations relating to: the levels of capital fees payable for applications for marketing authorizations, manufacturers' licences, wholesale dealers' licences, clinical trial certificates and export certificates; capital fees payable for variations and renewals of such authorizations, licences and certificates; periodic fees payable in connection with the holding of certain authorizations and licences; and the fees payable in connection with site inspections (regulation 4(5) and the Schedule). Fees have been increased by an average overall of 14%.

Regulation 5 revokes provisions of the Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1999 which are spent as a result of the coming into force of these Regulations.

A Regulatory Impact Assessment 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.

(**19**) O.J. No. L297, 13.10.92, p.8.
(**20**) O.J. No. L169, 12.7.93, p.1.