STATUTORY INSTRUMENTS

2006 No. 494

FEES AND CHARGES

MEDICINES

The Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2006

Made - - - -	*27th February 2006*
Laid before Parliament	*3rd March 2006*
Coming into force - -	*1st April 2006*

The Secretary of State for Health, the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, acting jointly, make the following Regulations in exercise of the powers conferred on them by section 1(1) and (2) of the Medicines Act 1971(**a**) or, as the case may be, the powers conferred by those provisions and now vested in them(**b**).

In so far as these Regulations are not made under section 1(1) and (2) of the Medicines Act 1971, the Secretary of State makes these Regulations in exercise of the powers conferred on her by section 2(2) of the European Communities Act 1972(**c**) and section 56(1) and (2) of the Finance Act 1973(**d**). The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to medicinal products(**e**).

The Treasury has consented to the making of these Regulations as required by section 1(1) of the Medicines Act 1971 and section 56(1) of the Finance Act 1973.

(**a**) 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); *see* therefore section 1(1) of the 1968 Act, as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, by article 5 of, and the Schedule to, S.I. 1999/3142, and by article 5(1) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794, 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.

(**b**) In the case of the Secretary of State, by virtue of article 2(1) of, and paragraph 1 of the Schedule to, S.I. 1999/3142 and article 3(1)(c) and (7) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794; and in the case of the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, by virtue of 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), which 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); the Departments were renamed by virtue of Article 3(4) and (6) of S.I. 1999/283 (N.I. 1).

(**c**) 1972 c.68.

(**d**) 1973 c. 51.

(**e**) S.I. 1972/181.

In accordance with section 129(6) of the Medicines Act 1968(**a**), the Secretary of State for Health, the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development have consulted with such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2006 and shall come into force on 1st April 2006.

(2) In these Regulations—

"the Devices Regulations" means the Medical Devices (Consultation Requirements)(Fees) Regulations1995(**b**);

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

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

Amendment of the General Fees Regulations

2.—(1) The General Fees Regulations are amended as follows.

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

(3) In Part II of Schedule 1 (capital fees for applications for authorizations, licences and certificates) (**e**), in paragraph 5, omit sub-paragraphs (1)(aa) and (3).

(4) In Part III of Schedule 1 (capital fees for applications for variations of authorizations, licences and certificates) (**f**), in paragraph 7—

(a) in sub-paragraph (a), at the end, insert "and"; and

(b) omit sub-paragraph (aa).

(5) In Schedule 2 (fees for inspections) (**g**), in paragraph 2—

(a) in sub-paragraph (d), at the end, insert "and"; and

(b) omit sub-paragraph (e).

(6) In Part III of Schedule 3 (periodic fees for marketing authorizations and licences(**h**), for sub-paragraph (1) of paragraph 7, substitute—

"(1) The fee payable under regulation 14(3) in connection with the holding of a manufacturer's licence shall be £356.".

Amendment of the Homoeopathic Products Regulations

3.—(1) The Homoeopathic Products Regulations are amended as follows.

(2) In regulation 14 (fees for variations of certificates)—

(**a**) 1968 c.67; section 129(6) was extended by section 1(3)(b) of the Medicines Act 1971.
(**b**) S.I. 1995/449 relevant amending instrument is S.I. 2004/666.
(**c**) S.I. 1995/1116, as amended by S.I. 1996/683, 1998/574, 1999/566, 2000/592 and 3031, 2001/795, 2002/236 and 542, 2003/625 and 2321, 2004/666 and 1157, and 2005/1124 and 2797.
(**d**) S.I. 1994/105 as amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2000/592, 2001/795, 2003/236 and 2321, 2004/666 and 2005/2753.
(**e**) Sub-paragraphs (1)(aa) and (3) were inserted by S.I. 2005/2979.
(**f**) Part III of Schedule 1 was amended by S.I.1996/683, 1998/574, 1999/566, 2000/592, 2001/795, 2002/236 and 542, 2003/625 and 2321, 2004/666 and 1157 and 2005/2979.
(**g**) Sub-paragraph (e) was inserted by S.I. 2005/2979.
(**h**) Paragraph 7 was substituted by S.I. 2005/2979.

(a) in paragraph (2)(a), for "£218" substitute "£226";

(b) in paragraph (2)(b)(i), for "£218" substitute "£226";

(c) in paragraph (2)(b)(ii), for "£218" substitute "£226";

(d) in paragraph (2)(b)(iii), for "£110" substitute "£114"; and

(e) in paragraph (2)(b)(iv), for "£55" substitute "£57".

(3) In the table in Schedule 2 (fees for applications for the grant of certificates of registration(**a**)—

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

(i) for "£134" substitute "£148";

(ii) for "£402" substitute "£444"; and

(iii) for "£664" substitute "£734"; and

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

(i) for "£330" substitute "£365";

(ii) for "£592" substitute "£654";

(iii) for "£869" substitute "£960".

Amendment of regulation 3 of the Devices Regulations

4.—(1) In regulation 3 of the Devices Regulations (fees)—

(a) in paragraph (1)(a), for "£3,575" substitute "£3,948";

(b) in paragraph (1)(b), for "£8,333" substitute "£9,202";

(c) in paragraph (2)(a), for "£707" substitute "£781";

(d) in paragraph (2)(b), for "£1,978" substitute "£2,184";

(e) in paragraph (3)(a), for "£3,575" substitute "£3,948";

(f) in paragraph (3)(b), for "£8,333" substitute "£9,262";

(g) in paragraph (4)(a), for "£707" substitute "£781";

(h) in paragraph 4(b), for "£1,978" substitute "£2,184";

(i) in paragraph (5)(a), for "£36,560" substitute "£40,374" and

(j) in paragraph (5)(b), for "£9,077" substitute "£10,024".

Signed by authority of the Secretary of State for Health

Jane Kennedy
Minister of State,
Department of Health

26th February 2006

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

Andrew McCormick
Permanent Secretary,
Department of Health, Social Services and Public Safety

23rd February 2006

(**a**) As amended by S.I.1996/482 and S.I. 2005/2753.

Sealed with the Official Seal of the Department of Agriculture and Rural Development

Pat Toal
Permanent Secretary,
23rd February 2006 Department of Agriculture and Rural Development

We consent,

Gillian Merron and Tom Watson
27th February 2006 Two of the Lords Commissioners of Her Majesty's Treasury

SCHEDULE

Regulation 2(1)

Column (1)	*Column (2)*	*Column (3)*	*Column (4)*
Provision in the General Fees Regulations	*Subject Matter*	*Old Amount*	*New Amount*
Regulation 3B(**a**)	Capital fees for pre-application meetings		
Paragraph (a)		£1,012	£1,118
Paragraph (b)		£1,346	£1,486
Paragraph (c)		£1,690	£1,866
Paragraph (d)		£2,024	£2,235
Regulation 3BA(**b**)	Capital fees for advertising advice meetings	£1,346	£1,486
Regulation 3BB(**c**)	Capital fees for pharmacovigilance advice meeting		
Paragraph (a)		£1,690	£1,866
Paragraph (b)		£1,346	£1,486
Regulation 3BC(**d**)	Capital fees for advice meetings concerning labelling and leaflets	£1,012	£1,118
Regulation 3BD(**e**)	Capital fees for post authorisation regulatory advice meetings	£1,346	£1,486
Regulation 6	Applications for certificates by exporters of medicinal products		
Paragraph (1)(a)		£118	£130
Paragraph (1)(b)		£53	£58
Paragraph (1)(c)(i)		£53	£58
Paragraph (1)(c)(ii)		£26	£29
Regulation 11	Renewal of certain manufacturer's licences	£127	£152

(**a**) Regulation 3B was inserted by S.I. 2003/625 and amended by S.I. 2003/2321 and 2004/666.
(**b**) Regulation 3BA was inserted by S.I. 2004/666.
(**c**) Regulation 3BB was inserted by S.I. 2004/666.
(**d**) Regulation 3BC was inserted By S.I. 2004/666.
(**e**) Regulation 3BD was inserted by S.I. 2004/666.

Part II of Schedule 1	Capital fees for applications for authorizations, licences and certificates		
In Column 2 of the Table in paragraph 1(**a**)	Entry 1(a)	£25,802	£28,494
	Entry 1(b)	£56,218	£61,959
	Entry 1(c)	£56,218	£61,959
	Entry 1(d)	£80,698	£88,993
	Entry 1(e)	£115,098	£126,982
	Entry 1(f)	£80,698	£88,993
	Entry 2(a)	£15,689	£17,202
	Entry 2(b)	£15,689	£17,202
	Entry 2(c)	£22,366	£24,576
	Entry 2(d)	£31,219	£34,353
	Entry 2(e)	£22,366	£24,576
	Entry 3(a)	£5,820	£6,304
	Entry 3(b)	£5,820	£6,304
	Entry 3(c)	£8,272	£9,011
	Entry 3(d)	£11,813	£12,921
	Entry 3(e)	£8,272	£9,011
	Entry 4(a)	£2,337	£2,457
	Entry 4(b)	£2,337	£2,457
	Entry 5	£1,493	£1,638
	Entry 6	£366	£404
	Paragraph 1A(1)	£6,558	£7,824
	Paragraph 4(4)(b)	£500	£594
	Paragraph 5(1)(a)	£142	£156
	Paragraph 5(1)(b)	£268	£295
	Paragraph 5(1)(c)	£2,444	£2,688
	Paragraph 6(1)	£1,402	£1,542
	Paragraph 6(2)	£600	£660
	Paragraph 6(4)	£310	£341
	In Column 2 of the Table in paragraph 7(**b**)		
	Entry 1	£610	£674
	Entry 2	£2,700	£2,982
	Entry 3	£2,250	£2,485
	Entry 4	£140	£155
Part IIA of Schedule 1(**c**)	Capital fees for assistance in obtaining marketing authorizations in other EEA States		
	Paragraph 2(a)(i)	£34,400	£37,989
	Paragraph 2(a)(ii)	£22,596	£24,953
	Paragraph 2(b)(i)	£8,853	£9,777
	Paragraph 2(b)(ii)	£5,902	£6,518
	Paragraph 2(c)(i)	£3,541	£3,910
	Paragraph 2(c)(ii)	£2,951	£3,259

(**a**) The Table was substituted by S.I. 2005/2979.
(**b**) Paragraph 7 was substituted by S.I. 2004/1157 and amended by S.I. 2005/1124.
(**c**) Part IIA was inserted by S.I. 2000/3031 and amended by S.I. 2001/795, 2002/236 and 242, 2003/625 and 2004/666.

Paragraph 2(d)		£2,119	£2,340
Part III of Schedule 1	Capital fees for applications for variations of authorizations, licences and certificates		
Paragraph 2(a)		£142	£170
Paragraph 2(aa)		£224	£266
Paragraph 2(b)		£590	£704
Paragraph 2(c)		£6,672	£7,964
Paragraph 2(cc)		£22,254	£24,576
Paragraph 2(d)		£6,558	£7,824
Paragraph 3(a)		£222	£264
Paragraph 3(aa)		£442	£526
Paragraph 3(b)		£714	£852
Paragraph 3(c)		£11,568	£13,808
Paragraph 3(d)		£31,106	£34,353
Paragraph 5A(1)		£500	£594
Paragraph 6(a)		£142	£158
Paragraph 6(b)		£6,558	£7,824
Paragraph 6(c)		£296	£326
Paragraph 7(a)		£200	£220
Paragraph 7(b)		£400	£440
Paragraph 8		£200	£220
Paragraph 9		£378	£416
Paragraph 10		£200	£220
Paragraph 11(1)(a)		£100	£110
Paragraph 11(1)(b)		£200	£220
Paragraph 11(1)(c)		£300	£330
Paragraph 15(a)(ii)		£500	£594
Paragraph 15(a)(iii)		£250	£297
Paragraph 15(b)(ii)		£250	£297
Part IIIA of Schedule 1(**a**)	Capital fees for assessment of labels and leaflets		
Paragraph 2(a)		£430	£472
Paragraph 2(b)		£273	£300
Part IV of Schedule 1(**b**)	Capital fees for regulatory assistance given by the United Kingdom acting as reference Member State relating to the assessment of applications for the renewal of specified marketing authorizations		
Paragraph 1(a)		£7,415	£8,847
Paragraph 1(b)		£605	£722
Paragraph 2(a)(ii)		£605	£722
Paragraph 2(b)(ii)		£303	£361
Schedule 2	Fees for inspections		
Paragraph 2(a)(i)		£2,534	£3,618
Paragraph 2(a)(ii)		£4,654	£6,645
Paragraph 2(a)(iii)		£5,610	£8,010

(**a**) Part IIIA was inserted by S.I. 2003/625 and amended by S.I. 2004/666, 2005/1124 and 2979.
(**b**) Part IV was inserted by S.I. 2002/542.

Paragraph 2(a)(iv)	£9,578	£13,676
Paragraph 2(b)(i)	£2,751	£3,928
Paragraph 2(b)(ii)	£5,610	£8010
Paragraph 2(b)(iii)	£8,782	£12,539
Paragraph 2(b)(iv)	£15,926	£22,740
Paragraph 2(c)(i)	£1,005	£1,563
Paragraph 2(c)(ii)	£2,717	£3,879
Paragraph 2(c)(iii)	£4,035	£5,761
Paragraph 2(c)(iv)	£7,512	£10,726
Paragraph 2(cc)(i)	£1,518	£2,243
Paragraph 2(cc)(ii)	£4,048	£5,856
Paragraph 2(cc)(iii)	£7,590	£10,914
Paragraph 2(d)	£221	£240
In column 2 in the Table in paragraph 2(f)(**a**)		
Entry for "none"	£1,023	£1,461
Entry for "1 to 4"	£1,226	£1,751
Entry for "5 to 20"	£2,035	£2,906
Entry for "21 to 100"	£4,059	£5,796
Entry for "101 to 500"	£9,119	£9,484
Entry for "more than 500"	£16,203	£16,850
Paragraph 4A(1)(b)	£3,000	£4,284
Paragraph 4A(1)(c)	£4,000	£5,712
Paragraph 5(1)	£499	£712
Paragraph 5(1)	£1,095	£1,563
In column 2 in the Table in paragraph 5(3)(**b**)		
Entry for "none"	£1,023	£1,461
Entry for "1 to 4"	£1,226	£1,751
Entry for "5 to 20"	£2,035	£2,906
Entry for "21 to 100"	£4,059	£5,796
Entry for "101 to 500"	£9,119	£9,484
Entry for "more than 500"	£16,203	£16,850
Paragraph 5A(a)(**c**)	£3,542	£5,057
Paragraph 5A(b)	£5,060	£7,225
Paragraph 5A(c)	£10,120	£14,450
Paragraph 5D(1)(a)(**d**)	£600	£800
Paragraph 5D(1)(b)	£1,100	£1,300
Paragraph 5D(1)(c)	£1,100	£1,300

(**a**) Paragraph 2(f) was inserted by S.I. 2005/2979.
(**b**) Paragraph 5(3) was inserted by S.I.2003/625.
(**c**) Paragraph 5A was inserted by S.I. 2003/625.
(**d**) Paragraph 5D was inserted by S.I. 2005/2979.

Paragraph 7(4)(a)(**a**)		£3,000	£4,284
Paragraph 7(4)(b)		£5,000	£7,139
Paragraph 7(4)(c)		£10,000	£14,279
Paragraph 7(4)(d)		£15,000	£21,418
Paragraph 7(4)		£3,000	£4,284
Part III of Schedule 3	Periodic fees for marketing authorizations and licences		
In column 2 of the Table in paragraph 1			
Entry 1		£14,768	£17,278
Entry 2(a)		£6,080	£7,114
Entry 2(b)(i)		£1,521	£1,780
Entry 2(b)(ii)		£759	£888
Entry 2(b)(iii)		£247	£289
Entry 2(c)(i)		£666	£779
Entry 2(c)(ii)		£333	£390
Entry 2(c)(iii)		£123	£144
Entry 2(d)(i)		£275	£322
Entry 2(d)(ii)		£137	£160
Entry 2(d)(iii)		£60	£70
Entry 2(e)		£75	£88
Paragraph 2(a)		£338	£395
Paragraph 2(b)		£167	£195
Paragraph 2(c)		£71	£83
Paragraph 3(a)		£6,080	£7,114
Paragraph 3(b)		£4,105	£4,803
Paragraph 7(2)		£304	£356
Paragraph 8(1)		£187	£219
Paragraph 8(2)		£112	£131
Paragraph 10(**b**)		£200	£234

(**a**) Paragraph 7 was inserted by S.I. 2004/1157.
(**b**) Paragraph 10 was inserted by S.I. 2004/1157.

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 Devices Regulations") and the Medicines (Products for Human Use—Fees) Regulations 1995 ("the General Fees Regulations").

The General Fees Regulations make provision for the fees payable under the Medicines Act 1971, and other fees payable in respect of Community obligations, relating to marketing authorizations, licences and certificates in respect of medicinal products for human use. Regulation 2 and the Schedule to these Regulations provide for a number of the fees payable by virtue of the General Fees Regulations to be increased. The increases are of amounts between 4% and 42.8%, Most capital fees have been increased by amounts between 10% and 19%, periodic fees have been increased by 17% and all but two of the inspection fees have been increased by 42.8% (the remaining two inspection fees have both been increased by 4%).

Regulation 2 also provides for certain provisions of the General Fees Regulations to be revoked. Those provisions provided for particular fees to be payable in respect of manufacturer's licences where those licences related solely to import of medicines from third countries. The revocation of those provisions means that the fees payable in respect of such licences will be the same as for other manufacturers' licences (i.e for manufacturer's licences which do not relate solely to import of medicines from third countries).

The Homoeopathic Products Regulations implemented in part Council Directive 92/73/EEC(**a**) (now replaced by Directive 2001/83/EC(**b**)) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for human use. Regulation 3 of these Regulations amends the Homoeopathic Products Regulations so as to increase the amounts of the fees payable for applications for, and variations of, certificates of registration and the fees payable by holders of certificates of registration. The increases average overall 10%.

The Devices Regulations prescribe the fees which are payable where a notified body consults the competent body in accordance with Council Directive 93/42/EEC(**c**) concerning medical devices. Regulation 4 of these Regulations amends the Devices Regulations by increasing the amounts of the fees specified in regulation 3 of those Regulations. The increases average overall 10%.

A full Regulatory Impact Assessment of the effect that this instrument will have on the costs of business has been placed in the libraries of both Houses of Parliament and copies may be obtained from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ

(**a**) OJ No. L 297, 13.10.1992, p.8.
(**b**) OJ No. L311, 28.11.2001, p.67;*See* articles 1(5), 13 to 16, 53, 68, 69, 85, 100, 119 and 124, Directive 2001/83/EC was amended by Council Directive 2004/27/EC (OJ No L136, 30.4. 2004, p.34)..
(**c**) OJ No. L 169, 12.7.1993, p.1; amended by Directive 98/79/EC (OJ No. L 331, 7.12.1998, p.1).

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