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 [M1] or, as the case may be, the powers conferred by those provisions and now vested in them [M2].

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 [M3] and section 56(1) and (2) of the Finance Act 1973 [M4]. 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 [M5].

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.

In accordance with section 129(6) of the Medicines Act 1968 [M6], 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.

Marginal Citations

M1 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.

M2 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).

M3 1972 c. 68.

M4 1973 c. 51.

M5 S.I. 1972/181.

M6 1968 c. 67; section 129(6) was extended by section 1(3)(b) of the Medicines Act 1971.

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 [M7];

"the General Fees Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995 [M8]; and

"the Homoeopathic Products Regulations" means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 [M9].

Marginal Citations

M7 S.I. 1995/449 relevant amending instrument is S.I. 2004/666.

M8 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.

M9 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.

Amendment of the General Fees Regulations

[F1]**2.** . . . . . .

Textual Amendments

F1 Reg. 2 revoked (1.4.2008) by The Medicines (Products for Human Use-Fees) Regulations 2008 (S.I. 2008/552), regs. 1, 48(1), **Sch. 7** (with reg. 48(2))

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) 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 [M10]—

(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 ".

Marginal Citations

M10 As amended by S.I.1996/482 and S.I. 2005/2753.

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

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

Department of Health, Social Services and Public Safety

Andrew McCormick
Permanent Secretary,

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

Department of Agriculture and Rural Development

Pat Toal
Permanent Secretary,

We consent,

Gillian Merron and Tom Watson
Two of the Lords Commissioners of Her Majesty's Treasury

[F2]SCHEDULE

Regulation 2(1)

Textual Amendments

F2 Sch. revoked (1.4.2008) by The Medicines (Products for Human Use-Fees) Regulations 2008 (S.I. 2008/552), regs. 1, 48(1), **Sch. 7** (with reg. 48(2))

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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).

[M11M12]The Homoeopathic Products Regulations implemented in part Council Directive 92/73/EEC (now replaced by Directive 2001/83/EC) 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%.

[M13]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 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

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2006.