STATUTORY INSTRUMENTS

# 2004 No. 666

# FEES AND CHARGES
# MEDICINES

## The Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2004

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| *Made - - - -* | *10th March 2004* |
| *Laid before Parliament* | *10th March 2004* |
| *Coming into force - -* | *1st April 2004* |

The Secretary of State, being a Minister designated for the purposes of section 2(2) of the European Communities Act 1972 [M1] in relation to medicinal products [M2], 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 [M3], the Secretary of State, 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 [M4], or, as the case may be, powers conferred by those provisions and now vested in them [M5], 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 [M6] with such organisations as appear to them to be representative of interests likely to be substantially affected, hereby make the following Regulations:

**Marginal Citations**

**M1** 1972 c. 68.

**M2** S.I. 1972/1811.

**M3** 1973 c. 51.

**M4** 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.

**M5** In the case of the Secretary of State, by virtue of articles 2(1) of, and paragraph 1 of the Schedule to, S.I. 1999/3142 and articles 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).

**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 2004 and shall come into force on 1st April 2004.

(2) In these Regulations—

"the Devices Regulations" means the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 [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; as amended by S.I. 1998/574, 1999/566, 2000/592, 2001/795, 2002/236 and 542, and 2003/625.

**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, and 2003/625 and 2321.

**M9** S.I. 1994/105; as amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2000/592, 2001/795, 2002/236 and 542, and 2003/625 and 2321.

## Amendment of the Homoeopathic Products Regulations

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

(2) In regulation 14 [M10] (fees for variations of certificates)—

(a) in paragraph (2)(a), for "£216" substitute " £218 ";

(b) in paragraph (2)(b)(i), for "£216" substitute " £218 ";

(c) in paragraph (2)(b)(ii), for "£216" substitute " £218 ";

(d) in paragraph (2)(b)(iii), for "£108" substitute " £110 "; and

(e) in paragraph (2)(b)(iv), for "£54" substitute " £55 ".

(3) In regulation 15(1) [M11] (fees payable by holders of certificates), for "£14" substitute " £15 ".

(4) In the Table in Schedule 2 [M12] (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 "£132" substitute " £134 ",

(ii) for "£397" substitute " £402 ", and

(iii) for "£656" substitute " £664 "; and

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

(i) for "£326" substitute " £330 ",

(ii) for "£585" substitute " £592 ", and

(iii) for "£859" substitute " £869 ".

**Marginal Citations**

**M10** As amended by regulation 2(2) of S.I. 2003/625.

**M11** As amended by regulation 2(3) of S.I. 2003/625.

**M12** As amended by regulation 2(4) of S.I. 2003/625.

### Amendment of regulation 3 of the Devices Regulations

**3.** In regulation 3 of the Devices Regulations [M13] (fees)—

(a) in paragraph (1)(a), for "£3,533" substitute " £3,575 ";

(b) in paragraph (1)(b), for "£8,234" substitute " £8,333 ";

(c) in paragraph (2)(a), for "£699" substitute " £707 ";

(d) in paragraph (2)(b), for "£1,955" substitute " £1,978 ";

(e) in paragraph (3)(a), for "£3,533" substitute " £3,575 ";

(f) in paragraph (3)(b), for "£8,234" substitute " £8,333 ";

(g) in paragraph (4)(a), for "£699" substitute " £707 ";

(h) in paragraph (4)(b), for "£1,955" substitute " £1,978 ";

(i) in paragraph (5)(a), for "£36,126" substitute " £36,560 "; and

(j) in paragraph (5)(b), for "£8,969" substitute " £9,077 ".

**Marginal Citations**

**M13** As amended by regulation 3 of S.I. 2003/625.

### Amendment of regulation 2 of the General Fees Regulations

**[F1]4.** . . . . . .

**Textual Amendments**

**F1** Regs. 4-15 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 Part IA of the General Fees Regulations

**[F1]5.** . . . . . .

**Textual Amendments**

**F1** Regs. 4-15 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 regulation 4 of the General Fees Regulations

**F1 6.** . . . . . .

**Textual Amendments**

**F1** Regs. 4-15 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 regulation 5 of the General Fees Regulations

**F1 7.** . . . . . .

**Textual Amendments**

**F1** Regs. 4-15 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 regulation 7 of the General Fees Regulations

**F1 8.** . . . . . .

**Textual Amendments**

**F1** Regs. 4-15 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 regulation 8 of the General Fees Regulations

**F1 9.** . . . . . .

**Textual Amendments**

**F1** Regs. 4-15 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 regulation 13 of the General Fees Regulations

**F1 10.** . . . . . .

**Textual Amendments**

**F1** Regs. 4-15 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 Part VII of the General Fees Regulations

**F1 11.** . . . . . .

**Textual Amendments**

**F1** Regs. 4-15 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 Part I of Schedule 1 to the General Fees Regulations

**F1 12.** . . . . . .

**Textual Amendments**

**F1** Regs. 4-15 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 Schedule 2 to the General Fees Regulations

**F1 13.** . . . . . .

**Textual Amendments**

**F1** Regs. 4-15 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 Schedule 5 to the General Fees Regulations

**F1 14.** . . . . . .

**Textual Amendments**

**F1** Regs. 4-15 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 General Fees Regulations

**F1 15.** . . . . . .

**Textual Amendments**

**F1** Regs. 4-15 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))

Signed by authority of the Secretary of State for Health

*Warner*
Parliamentary Under Secretary of State,Department of Health

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

*GowdyD. C.*
Permanent Secretary,Department of Health, Social Services and Public Safety

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

*Pat Toal*
Permanent Secretary, Department of Agriculture and Rural Development

We consent,

*Derek Twigg*
*Nick Ainger*
Two of the Lords Commissioners of Her Majesty's Treasury

## [F2]SCHEDULE

Regulation 15

**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))

[F2] . . . . . .

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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 Homoeopathic Products Regulations implemented in part Council Directive 92/73/EEC (now repealed and re-enacted in Directive 2001/83/EC) 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 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. These increases average overall 3.7 per cent.

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 3 of these Regulations amends the Devices Regulations by increasing the amounts of the fees specified in regulation 3 of those Regulations by an average overall of 3.7 per cent.

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. Regulations 4 to 14 of these Regulations amend those Regulations as follows.

Regulations 4(a) and (b), 6 to 10 and 13 make provision for fees for inspections of contract laboratories. Regulations 6 to 10 amend the provisions for fees for inspections so as to provide that when an inspection is made of a contract laboratory the fee for that inspection is payable by the operator of the laboratory. Regulation 13 introduces the new fee for inspections of contract laboratories.

Regulations 4(c) and 11 make provision for new penalty fees for late payment of periodic fees.

Regulation 5 amends regulation 3A of the General Fees Regulations and inserts new regulations to make provision for new fees for meetings at which the licensing authority provide pharmacovigilance, advertising, or regulatory advice, or advice on proposed changes to labelling or package leaflets, to holders of marketing authorizations or to potential applicants for a marketing authorization. Regulation 14 makes provision for the waiver of fees payable in connection with these meetings where the meeting has been held at the request of the licensing authority.

Regulation 12 amends the definition of a complex application in Part I of Schedule 1 to the General Fees Regulations to add a new category of complex application as a consequence of the adoption of Commission Directive 2003/63/EC, which amends Directive 2001/83/EC

by substituting a new Annex I setting out standards and protocols in respect of the testing of medicinal products for which applications for marketing authorization are made.
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; capital fees payable for pre-application meetings; periodic fees payable in connection with the holding of certain authorizations and licences; and the fees payable in connection with site inspections (regulation 15 and the Schedule to these Regulations). There have been adjustments to specific capital fees, some increases and three reductions, plus a general 1.2 per cent increase, which together represent an overall 3.7 per cent increase in capital fees. Periodic fees have been increased by 3.7 per cent.
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 and Healthcare products Regulatory Agency, Room 16-107, 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 2004.