STATUTORY INSTRUMENTS

# 2004 No. 666

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

# 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<sup>M1</sup>;

"the General Fees Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995 <sup>M2</sup>; and

"the Homoeopathic Products Regulations" means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994<sup>M3</sup>.

#### **Marginal Citations**

- M1 S.I. 1995/449; as amended by S.I. 1998/574, 1999/566, 2000/592, 2001/795, 2002/236 and 542, and 2003/625.
- M2 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.
- **M3** 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 <sup>M4</sup> (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)<sup>M5</sup> (fees payable by holders of certificates), for "£14" substitute " £15".
- (4) In the Table in Schedule 2<sup>M6</sup> (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**

- M4 As amended by regulation 2(2) of S.I. 2003/625.
- M5 As amended by regulation 2(3) of S.I. 2003/625.
- M6 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<sup>M7</sup> (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**

M7 As amended by regulation 3 of S.I. 2003/625.

## Amendment of regulation 2 of the General Fees Regulations

#### **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

*Changes to legislation:* There are currently no known outstanding effects for the The Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2004. (See end of Document for details)

#### **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

#### **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

#### **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

#### **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

#### **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

#### **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

## **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

#### **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

#### **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

#### **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**

Changes to legislation: There are currently no known outstanding effects for the The Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2004. (See end of Document for details)

# 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

**Changes to legislation:** There are currently no known outstanding effects for the The Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2004.