STATUTORY INSTRUMENTS

1999 No. 566

The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1999

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 1999 and shall come into force on 1st April 1999.

(2) In these Regulations–

"the General Fees Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995 [M1];

"the Homoeopathic Products Regulations" means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 [M2].

Marginal Citations

M1 S.I. 1995/1116; amended by S.I. 1996/683 and 1998/574.

M2 S.I. 1994/105; amended by S.I. 1995/541, 1996/482 and 1998/574.

Amendment of the Homoeopathic Products Regulations

2.—(1) In regulation 14 of the Homoeopathic Products Regulations [M3] (fees for variations of certificates)–

(a) in paragraph (1)(a), for "£75" there shall be substituted " £80 ";

(b) in paragraph (1)(b)(i), for "£75" there shall be substituted " £80 ";

(c) in paragraph (1)(b)(ii), for "£37.50" there shall be substituted " £40 ";

(d) in paragraph (2)(a), for "£150" there shall be substituted " £155 ";

(e) in paragraph (2)(b)(i), for "£150" there shall be substituted " £155 "; and

(f) in paragraph (2)(b), for heads (ii) and (iii) there shall be substituted the following heads–

"(ii) in respect of each other application so considered, where further medical, technical or scientific assessment is required, a fee of £155,

(iii) in respect of the second to thirtieth applications so considered, where no further medical, technical or scientific assessment is required, a fee of £77.50, and

(iv) in respect of each other application so considered, where no further medical, technical or scientific assessment is required, a fee of £38.75.".

(2) In the Table in Schedule 2 to the Homoeopathic Products Regulations (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 "£90" there shall be substituted " £95 ",

(ii) for "£270" there shall be substituted " £285 ", and

(iii) for "£450" there shall be substituted " £470 "; and

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

(i) for "£225" there shall be substituted " £235 ",

(ii) for "£400" there shall be substituted " £420 ", and

(iii) for "£585" there shall be substituted " £615 ".

Marginal Citations

M3 *See* regulation 2(3) of S.I. 1998/574.

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 [M4] (fees)–

(a) in paragraph (1)(a), for "£1,910" there shall be substituted " £2,005 ";

(b) in paragraph (1)(b), for "£5,355" there shall be substituted " £5,620 ";

(c) in paragraph (2)(a), for "£475" there shall be substituted " £500 ";

(d) in paragraph (2)(b), for "£1,335" there shall be substituted " £1,400 ";

(e) in paragraph (3)(a), for "£1,910" there shall be substituted " £2,005 ";

(f) in paragraph (3)(b), for "£5,355" there shall be substituted " £5,620 ";

(g) in paragraph (4)(a), for "£475" there shall be substituted " £500 ";

(h) in paragraph (4)(b), for "£1,335" there shall be substituted " £1,400 ";

(i) in paragraph (5)(a), for "£24,500" there shall be substituted " £25,725 "; and

(j) in paragraph (5)(b), for "£6,120" there shall be substituted " £6,425 ".

Marginal Citations

M4 S.I. 1995/449; the relevant amending instrument is S.I. 1998/574.

Amendment of the General Fees Regulations

4.—(1) In paragraph 6(a) of Part III of Schedule 1 to the General Fees Regulations (capital fees for applications for, and variations to, marketing authorizations, licences and certificates—fees payable in connection with an application for variation of a marketing authorization (parallel import)), after head (vi) [M5] there shall be inserted the following head–

"(vii) subject to paragraph 6(b) of Schedule 5, a change consequential upon any or any combination of the following–

(aa) a change of ownership of the United Kingdom marketing authorization in respect of which the marketing authorization (parallel import) was granted,

(bb) a change to the number of the United Kingdom marketing authorization in respect of which the marketing authorization (parallel import) was granted,

(cc) a change to the name of the holder of the United Kingdom marketing authorization in respect of which the marketing authorization (parallel import) was granted,

(dd) a change to the address of the holder of the United Kingdom marketing authorization in respect of which the marketing authorization (parallel import) was granted,

(ee) a change of ownership of the marketing authorization for the product in the country where the product originates,

(ff) a change to the number of the marketing authorization for the product in the country where the product originates,

(gg) a change to the name of the holder of the marketing authorization for the product in the country where the product originates,

(hh) a change to the address of the holder of the marketing authorization for the product in the country where the product originates,

where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise,".

(2) 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.

Marginal Citations

M5 Inserted by regulation 5(4) of S.I. 1996/683.

Revocation

5. Regulation 2(5) and 3 of the Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1998 [M6] are hereby revoked.

Marginal Citations

M6 S.I. 1998/574.

Signed by authority of the Secretary of State for Health

Hayman
Parliamentary Under Secretary of State,
Department of Health

25th February 1999

Signed by authority of the Secretary of State for Wales

Jon Owen Jones
Parliamentary Under Secretary of State, Welsh Office

5th March 1999

Sam Galbraith
Parliamentary Under Secretary of State, Scottish Office

25th February 1999

Jeff Rooker
Minister of State, Ministry of Agriculture, Fisheries and Food

25th February 1999

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on

L.S.

D.C. Gowdy
Permanent Secretary

1st March 1999.

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on

L.S.

P. Small
Permanent Secretary

24th February 1999.

We consent,

Bob Ainsworth
Jim Dowd
Two of the Lords Commissioners of Her Majesty's Treasury

3rd March 1999

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1999. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Regulations revoked by S.I. 2013/532 Sch. 9
- reg. 2(1)(a)-(e) revoked by S.I. 2000/592 reg. 5
- reg. 2(2) revoked by S.I. 2000/592 reg. 5
- reg. 3 revoked by S.I. 2000/592 reg. 5
- reg. 4(2) revoked by S.I. 2000/592 reg. 5