
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(1);

“the Homoeopathic Products Regulations” means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(2).

Amendment of the Homoeopathic Products Regulations

2.—(1) In regulation 14 of the Homoeopathic Products Regulations(3) (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

(1) S.I.1995/1116; amended by S.I. 1996/683 and 1998/574.

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

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

- (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”.

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(4) (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”.

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)(5) 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,

(4) S.I. 1995/449; the relevant amending instrument is S.I. 1998/574.

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

(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.

Revocation

5. Regulation 2(5) and 3 of the Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1998(6) are hereby revoked.

Signed by authority of the Secretary of State for Health

25th February 1999

Hayman
Parliamentary Under Secretary of State,
Department of Health

Signed by authority of the Secretary of State for Wales

5th March 1999

Jon Owen Jones
Parliamentary Under Secretary of State, Welsh
Office

25th February 1999

Sam Galbraith
Parliamentary Under Secretary of State, Scottish
Office

25th February 1999

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

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

L.S.

1st March 1999.

D.C. Gowdy
Permanent Secretary

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

L.S.

24th February 1999.

P. Small
Permanent Secretary

We consent,

3rd March 1999

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