STATUTORY INSTRUMENTS

2000 No. 592

The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 2000

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 2000 and shall come into force on 1st April 2000.

(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 "£80" there shall be substituted " £90";

(b) in paragraph (1)(b)(i), for "£80" there shall be substituted " £90";

(c) in paragraph (1)(b)(ii), for "£40" there shall be substituted " £45";

(d) in paragraph (2)(a), for "£155" there shall be substituted " £176";

(e) in paragraph (2)(b)(i), for "£155" there shall be substituted " £176";

(f) in paragraph (2)(b)(ii), for "£155" there shall be substituted " £176";

(g) in paragraph (2)(b)(iii), for "£77.50" there shall be substituted " £88"; and

(h) in paragraph (2)(b)(iv), for "£38.75" there shall be substituted " £44".

(2) In regulation 15(1) of the Homoeopathic Products Regulations(**4**) (fee payable by holders of certificates), for "£10" there shall be substituted "£11".

(3) In the Table in Schedule 2 to the Homoeopathic Products Regulations(**5**) (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 "£95" there shall be substituted "£108",

(ii) for "£285" there shall be substituted "£325", and

(iii) for "£470" there shall be substituted "£535"; and

(**1**) S.I.1995/1116; amended by S.I. 1996/683, 1998/574 and 1999/566.
(**2**) S.I. 1994/105; amended by S.I. 1995/541, 1996/482, 1998/574 and 1999/566.
(**3**) As amended by regulation 2(3) of S.I. 1998/574 and regulation 2(1) of S.I. 1999/566.
(**4**) As amended by regulation 2(4) of S.I. 1998/574.
(**5**) As amended by regulation 2(2) of S.I. 1999/566.

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

(i) for "£235" there shall be substituted "£267",

(ii) for "£420" there shall be substituted "£478", and

(iii) for "£615" there shall be substituted "£701".

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(**6**) (fees)–

(a) in paragraph (1)(a), for "£2,005" there shall be substituted " £2,285";

(b) in paragraph (1)(b), for "£5,620" there shall be substituted " £6,406";

(c) in paragraph (2)(a), for "£500" there shall be substituted " £570";

(d) in paragraph (2)(b), for "£1,400" there shall be substituted " £1,596";

(e) in paragraph (3)(a), for "£2,005" there shall be substituted " £2,285";

(f) in paragraph (3)(b), for "£5,620" there shall be substituted " £6,406";

(g) in paragraph (4)(a), for "£500" there shall be substituted " £570";

(h) in paragraph (4)(b), for "£1,400" there shall be substituted " £1,596";

(i) in paragraph (5)(a), for "£25,725" there shall be substituted " £29,326"; and

(j) in paragraph (5)(b), for "£6,425" there shall be substituted " £7,324".

Amendment of the General Fees Regulations

4.—(1) In paragraph (1) of regulation 2 of the General Fees Regulations(**7**) (interpretation), after the definition of "medicinal product" there shall be inserted the following definition–

""orphan medicinal product" has the meaning given in article 2(b) of Regulation (EC) No. 141/2000(**8**) of the European Parliament and of the Council of 16th December 1999 on orphan medicinal products;".

(2) In Column 1 of the Table set out in paragraph 1 of Part II of Schedule 1 to the General Fees Regulations (which contains a list of types of application for a marketing authorization in connection with which a capital fee is payable), for the words "any such application" in entry 1(a) there shall be substituted the words "any application relating to an orphan medicinal product or a product".

(3) In the following provisions–

(a) paragraphs 4 and 5 of Part III of Schedule 1 to the General Fees Regulations (which relate to the capital fee payable for the first application for a variation of a marketing authorization granted in respect of a limited use drug); and

(b) paragraph 1 of Part I of Schedule 3 to the General Fees Regulations(**10**) (interpretation of Schedule 3),

after the words "Directive 75/318/EEC(**9**) applies", at each place where they occur, there shall be inserted the words "or which is in respect of an orphan medicinal product".

(**6**) S.I. 1995/449; as amended by regulation 3 of S.I. 1999/566.
(**7**) As amended by regulation 2 of S.I. 1996/683.
(**8**) O.J. No. L18, 22.1.2000, p.1.
(**10**) As amended by regulation 6(1) of S.I. 1996/683.
(**9**) O.J. No. L147, 9.6.1975, p.1. This Directive has been amended by Council Directive 95/319/EEC (O.J. No. L147, 9.6.1975, p.13), Council Directive 83/570/EEC (O.J. No. L332, 28.11.1983, p.1), Council Directive 87/19/EEC (O.J. No. L15, 17.1.1987, p.31), Council Directive 89/341/EEC (O.J. No. L142, 25.5.1989, p.11), Commission Directive 91/507/EEC (O.J.

(4) In paragraph 4 of Part III of Schedule 3 to the General Fees Regulations(**11**) (which relates to the periodic fees payable in connection with the holding of certain marketing authorizations)–

(a) before sub-paragraph (3) there shall be inserted the following sub-paragraph–

"(2A) The fee payable in respect of–

(a) a new active substance in accordance with entry 1 of the Table set out in paragraph 1; or

(b) a derivative of a new active substance in accordance with paragraph 3,

shall only be payable for the five relevant fee periods following the fee period during which the marketing authorization was granted.";

(b) in sub-paragraph (4)(a), for the words "each fee period mentioned in sub-paragraph (1)," there shall be substituted the words "the five relevant fee periods following the fee period during which the marketing authorization was granted,";

(c) in sub-paragraph (5), for the words "sub-paragraphs (1), (2) and (3) " there shall be substituted the words "sub-paragraphs (2A) to (4)"; and

(d) for sub-paragraph (6) there shall be substituted the following sub-paragraph–

"(6) In connection with the holding of a marketing authorization in respect of a limited use drug or a derivative of a limited use drug–

(a) where turnover exceeds £200,000, until the expiry of the five relevant fee periods following the fee period during which the marketing authorization was granted, the periodic fee payable shall be the fee that would be payable if the drug were, respectively, a new active substance or a derivative of a new active substance;

(b) where turnover does not exceed £200,000 or where a periodic fee has been payable in respect of the limited use drug or derivative of a limited use drug for five relevant fee periods following the fee period during which the marketing authorization was granted, the periodic fee payable shall be the fee payable in respect of a prescription only medicine in accordance with entry 2(b)(i) of the Table set out in paragraph 1.".

(5) 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. Regulations 2(1)(a) to (e) and (2), 3 and 4(2) of Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 1999(**12**) are hereby revoked.

No. L270, 26.9.1991, p.32), Council Directive 93/39/EEC (O.J. No. L214, 24.8.93, p.22), Commission Directive 1999/82/EC (O.J. No. L243, 15.9.1999, p.7) and Commission Directive 1999/83/EC (O.J. No. L243, 15.9.1999, p.9).

(**11**) As amended by regulation 6(3) of S.I. 1996/683.

(**12**) S.I. 1999/566.

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
1st March 2000 Department of Health

Hayman
Minister of State, Ministry of Agriculture,
6th March 2000 Fisheries and Food

D.C. Gowdy
Permanent Secretary,
Department of Health, Social Services and
6th March 2000 Public Safety

P. Small
Permanent Secretary,
Department of Agriculture and Rural
3rd March 2000 Development

We consent,

Bob Ainsworth
Greg Pope
Two of the Lords Commissioners of Her
6th March 2000 Majesty's Treasury