STATUTORY INSTRUMENTS

1996 No. 683

MEDICINES

The Medicines (Products for Human Use —Fees) Amendment Regulations 1996

Made - - - -	*7th March 1996*
Laid before Parliament	*8th March 1996*
Coming into force - -	*1st April 1996*

The Secretary of State concerned with health in England, the Secretaries of State concerned with health and with agriculture in Wales and in Scotland respectively, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, with the consent of the Treasury, in exercise of powers conferred upon them by section 1(1) and (2) of the Medicines Act 1971(**1**), or, as the case may be, those conferred by the said provisions and now vested in them(**2**), and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations(**3**), hereby make the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Products for Human Use—Fees) Amendment Regulations 1996 and shall come into force on 1st April 1996.

(2) In these Regulations "the principal Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995(**4**).

(**1**) 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 in that section have the same meaning as in the Medicines Act 1968 (c. 67), as amended by the Transfer of Functions (Wales) Order 1969 (S.I.1969/388). The expression "the Ministers" is defined in section 1(1) of the 1968 Act as so amended. By virtue of regulation 9(12) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144), references in section 1(1) and (2)(b) to a licence under Part II of the 1971 Act include a reference to a marketing authorization under those Regulations.

(**2**) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969; in the case of the Secretary of State concerned with agriculture in Wales by virtue of article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272); in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(**3**) *See* section 129(6) of the Medicines Act 1968 (c. 67) as extended to include regulations made under the Medicines Act 1971 by section 1(3)(b) of the latter Act.

(**4**) S.I. 1995/1116.

Amendment of regulation 2 of the principal Regulations

2. In regulation 2(1) (interpretation) of the principal Regulations, for the definition of"change of ownership application" substitute—

""change of ownership application" means an application—

(a) for—

(i) a marketing authorization for a medicinal product in respect of which another person holds a marketing authorization;

(ii) a manufacturer's licence for activities in respect of which another person holds a manufacturer's licence; or

(iii) a wholesale dealer's licence for activities in respect of which another person holds a wholesale dealer's licence;

(b) which refers to particulars which are in all material respects identical to the particulars of the marketing authorization, manufacturer's licence, or wholesale dealer's licence which is held by that other person; and

(c) which includes a statement to the effect that that other person intends to cease the activities to which his marketing authorization or licence relates and has consented in writing to the making of the application.

and in this definition particulars do not include particulars relating to the name and address of the applicant, the labelling of any medicinal product or the content of any leaflet relating to such a product;".

Amendment of amounts specified in the principal Regulations

3. In each provision of the principal 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) substitute the amount specified opposite that provision in column (4).

Amendment of regulation 14 of the principal Regulations

4. In regulation 14 (periodic fees) of the principal Regulations—

(a) in paragraph (4) omit "or licence";

(b) at the end add the following paragraph—

"(6) No periodic fee shall be payable in respect of the fee period during which a manufacturer's or wholesale dealer's licence is first granted except where—

(a) that licence is granted pursuant to a change of ownership application; and

(b) no periodic fee has been paid in respect of that fee period in connection with the manufacturer's or wholesale dealer's licence which is mentioned in that application in the statement of intention to cease activities.".

Amendment of Schedule 1 to the principal Regulations

5.—(1) For paragraph 5(1)(b) (manufacturer's licences) of Part II of Schedule 1 (capital fees for applications for marketing authorizations, licences and certificates) to the principal Regulations substitute—

"(b) in the case of a change of ownership application, £180;

(c) in any other case, £1,690.".

(2) In paragraph 6 (wholesale dealer's licences) of Part II of Schedule 1 to the principal Regulations—

(a) in sub-paragraph (1) for "sub-paragraph (2)" substitute "sub-paragraphs (2) and (4)";

(b) in sub-paragraph (2) for "The fee payable" substitute "Subject to paragraph (4), the fee payable";

(c) after sub-paragraph (3) add

"(4) The fee payable under regulation 4(a) in connection with a change of ownership application shall be £210.".

(3) In paragraph 1 (marketing authorizations) of Part III (capital fees for variations) of Schedule 1 to the principal Regulations—

(a) in the definition of "Type II Application" omit "or a product licence of right";

(b) in the definition of "Type II complex variation"—

(i) in sub-paragraph (a) after "following" insert "changes, other than a change to which paragraph 1 (changes to active substances) or paragraph 3 (changes to strength, pharmaceutical form and route of administration) of Annex II to Commission Regulation (EC) No. 541/95(**5**) applies";

(ii) at the end of sub-paragraph (b) insert "or";

(iii) for sub-paragraph (c) substitute—

"(c) in the composition, manufacture or use of a medicinal product to which—

(i) paragraph (c), (e), (g), (h), (j) or (n) of the definition of complex application in this Schedule would apply where an application for a marketing authorization is made in respect of a medicinal product; or

(ii) paragraph (i) of that definition would so apply and the change is not a minor variation which satisfies the condition specified in point 11 (specifications, synthetic route and quality control procedures the same as those already approved or a European Pharmacopoeia Certificate of suitability covering the active substance submitted) of Annex I to Commission Regulation (EC) No. 541/95.".

(4) In paragraph 6(a) (fees for variation of marketing authorizations (parallel import)) of Part III of Schedule 1, after sub-paragraph (v) insert the following sub-paragraph—

"(vi) the addition or deletion of the name and address of the suppliers of the medicinal product to which the authorization relates, or a change in the name, the address, or both the name and address, of the suppliers of that product;".

Amendment of Schedule 3 to the principal Regulations

6.—(1) In paragraph 1 (interpretation) of Part I of Schedule 3 (periodic fees) to the principal Regulations, in the definition of "maintenance fee", in sub-paragraph (b) for "the relevant calendar year" substitute "that period".

(2) For paragraph 3 (derivatives of new active substances) of Part III (periodic fees for marketing authorizations and licences) of Schedule 3 to the principal Regulations substitute—

"**3.** Subject to paragraph 4, where a marketing authorization is held in respect of a derivative of a new active substance, the fee payable under regulation 14(3) shall be—

(**5**) OJ No. L55, 11.3.95, p. 7.

(a) where it has a different route of administration from that of the new active substance, £4,800;

(b) in any other case, £3,400.".

(3) In paragraph 4 (transitional arrangements for periodic fees) of Part III of Schedule 3 to the principal Regulations omit sub-paragraphs (1) and (2).

(4) In Part IV (marketing authorizations for which a single periodic fee is payable) of Schedule 3 to the principal Regulations omit paragraph 2 (homoeopathic or anthroposophic products).

Amendment of Schedule 5 to the principal Regulations

7.—(1) In paragraph 3(1)(c) (withdrawal of application after a request to supply information) of Schedule 5 (waiver, reduction or refund of capital fees) to the principal Regulations, after "of the Act" insert "or in pursuance of a Community provision which applies to applications for marketing authorizations".

(2) After paragraph 4 (fees for manufacturer's and wholesale dealer's licences) of Schedule 5 to the principal Regulations insert—

"**4A.**—(1) Where an application for the grant of a marketing authorization or a clinical trial certificate is refused by the licensing authority and—

(a) the information contained in it, or submitted with it, was not sufficient to enable a full medical, scientific or pharmaceutical assessment to be undertaken; and

(b) if the applicant had withdrawn it before it was refused, part of the fee payable in respect of it would have been refunded or waived under paragraph 3;

there shall be refunded or waived the amount which would have been refunded or waived if the application had been withdrawn before it was refused by the licensing authority.".

(3) In Schedule 5 to the principal Regulations omit paragraph 6(3) (fees for variations).

(4) After paragraph 6 of Schedule 5 to the principal Regulations insert—

"**7.**—(1) Subject to sub-paragraphs (2) and (3), where an applicant applies to vary a marketing authorization in the circumstances set out in paragraph 4(4) of Part III of Schedule 3, the fee payable under regulation 7(1) shall be refunded or waived.

(2) Subject to paragraph (3), where an applicant on the same occasion submits more than one such application which relates to medicinal products containing the same active ingredients but no other active ingredient, sub-paragraph (1) shall apply only to one of those applications.

(3) Where in respect of any two or more of the applications mentioned in sub-paragraph (2) provision is made for fees of different amounts by paragraphs 13 and 14 of Part III of Schedule 1, sub-paragraph (1) shall apply to the application in respect of which those paragraph makes provision for the higher or highest fee".

Signed by authority of the Secretary of State for Health

Gerald Malone
Minister of State
Department of Health

22nd February 1996

William Hague
27th February 1996 Secretary of State for Wales

James Douglas Hamilton
27th February 1996 Minister of State, Scottish Office

Angela Browning
Parliamentary Secretary, Ministry of Agriculture,
5th March 1996 Fisheries and Food

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

L.S.

F. A. Elliott
28th February 1996. Permanent Secretary

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

L.S.

J. Murray
26th February 1996. Permanent Secretary

We consent,

Derek Conway
Simon Burns
Two of the Lords Commissioners of Her
7th March 1996. Majesty's Treasury

SCHEDULE Regulation 3

Column (1) Provision in the principal Regulations	Column (2) Subject matter	Column (3) Old amount	Column (4) New amount
Regulation 6	applications for certificates by exporters		
Regulation 6(1)(a)		£120	£110
Regulation 6(1)(b)		£60	£55
Regulation 6(1)(c)(i)		£60	£55
Regulation 10	renewals of clinical trial certificates	£2,405	£1,925
Schedule 1, Part II	capital fees for applications for authorizations, licences and certificates		
paragraph 1, in Column 2 of the Table			
entry 2(a)		£10,305	£11,080
entry 2(b)		£14,725	£15,830
entry 3(a)		£4,255	£4,045
entry 3(b)		£6,080	£5,775
entry 5		£1,700	£1,490
entry 6		£790	£750
paragraph 7		£14,465	£11,600
Schedule 1, Part III	capital fees for applications for variations of authorizations, licences and certificates		
paragraph 11		£240	£195
paragraph 12		£90	£75
Schedule 2	fees for inspections		
paragraph 2(a)(iv)		£9,025	£8,125
paragraph 2(b)(ii)		£4,890	£4,650
paragraph 2(b)(iii)		£7,885	£7,100
paragraph 2(b)(iv)		£15,010	£13,510
paragraph 2(c)(iii)		£2,790	£2,510

Column (1) Provision in the principal Regulations	Column (2) Subject matter	Column (3) Old amount	Column (4) New amount
paragraph 2(c)(iv)		£5,225	£4,700
Schedule 3, Part III, paragraph 1, Column 2 of the Table	periodic fees		
entry 1		£11,900	£11,300
entry 2(a)		£5,950	£4,800
entry 2(b)(i)		£1,075	£1,130
entry 2(b)(ii)		£535	£560
entry 2(b)(iii)		£180	£190
entry 2(f)		£30	£11

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Products for Human Use—Fees) Regulations 1995 ("the principal Regulations"). The principal Regulations make provision for the fees payable under the Medicines Act 1971 in respect of marketing authorizations, licences and certificates relating to medicinal products for human use.

These Regulations (regulation 3 and the Schedule) vary some of the fees payable for applications for marketing authorizations, clinical trial certificates and export certificates; for variations and renewals of clinical trial certificates; and periodic fees in connection with the holding of such authorizations and licences. They also vary the fees payable in respect of inspections of sites carried out in connection with applications for, or during the currency of, such authorizations and licences. The overall effect of these changes is a reduction of 2 per cent. in fee levels. Some application fees and inspection fees are reduced by 5 or 20 per cent.; the capital fee for complex applications is increased by 7.5 per cent. Periodic fees relating to new and complex drugs are reduced by 5 and 20 per cent. respectively; those for prescription only medicines are increased by 5 per cent.

These Regulations also make a number of miscellaneous amendments:

— regulation 2 extends the definition of "change of ownership application" to include certain applications for manufacturer's or wholesale dealer's licences; regulation 4 makes provision for the continuation of periodic fees where such applications are made and regulation 5(1) and (2) introduces capital fees of £180 and £210 (that is, reductions respectively of £1,510 and £570 from the fees which would otherwise be payable in the case of applications for manufacturer's and wholesale dealer's licences);

— regulation 5(3)(a) amends the definition of "Type II Application" so as to permit the fees for such variations to apply to the variation of product licences of right and regulation 5(3)(b) amends the definition of "Type II complex variation" so as to exclude from that definition—

(a) changes to medicinal products which can only be authorized where an application for a further marketing authorization is made (*see* Commission Regulation (EC) No. 541/95, OJ No. L55, 11.3.95, p. 7); and

(b) certain applications relating to new manufacturers of active ingredients;

— regulation 6(1) amends the definition of "maintenance fee" to provide that in calculating such a fee regard is had to a fee period rather than to a calendar year; regulation 6(2) aligns the categories of fee payable for the variation of marketing authorizations with those which apply on the grant of such authorizations and in place of fees of £5,950 and £3,575 introduces fees of £4,800 and £3,400; regulation 6(3) removes spent transitional provisions; and regulation 6(4) removes a provision under which a single fee has applied to several marketing authorizations which relate to homoeopathic or anthroposophic products derived from the same mother tincture or combination of mother tinctures;

— regulation 7 makes further provision for the partial refund or waiver of fees where applications are withdrawn, cannot be assessed or where the provisions of one marketing authorization are included in another.

An assessment of the cost to business of complying with these Regulations has been made, copies of which have been placed in the libraries of both Houses of Parliament and further copies of which may be obtained from the Medicines Control Agency, Department of Health, Room 1207, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.