STATUTORY INSTRUMENTS

1992 No. 756

MEDICINES

The Medicines (Products for Human Use– Fees) Amendment Regulations 1992

Made - - - -	*12th March 1992*
Laid before Parliament	*13th March 1992*
Coming into force	
for the purpose of regulation 2 and the Schedule	*1st April 1992*
for all other purposes	*3rd April 1992*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and in Scotland, 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 1992, and shall come into force for the purposes of regulation 2 and the Schedule on 1st April 1992 and for all other purposes on 3rd April 1992.

(**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 insection 1(1) of the 1968 Act as so amended.

(**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 that latter Act.

(2) In these Regulations, "the principal Regulations" means the Medicines (Products for Human Use– Fees) Regulations 1991(**4**).

Amendment of amounts specified in the principal Regulations

2. For each amount specified in column (3) of the Schedule to these Regulations, where it appears in the provision of the principal Regulations specified in relation to it in column (1) of the Schedule (the subject matter of which is indicated in column (2) of the Schedule), there is substituted the amount specified in relation to it in column (4) of the Schedule.

Amendment of regulation 2 of the principal Regulations

3.—(1) Regulation 2 of the principal Regulations (interpretation) shall be amended in accordance with the following paragraphs of this regulation.

(2) In paragraph (1)–

(a) after the definition of "the Act", there shall be inserted the following–

> ""blood product" means any medicinal product derived from human blood or human plasma and shall include albumin, coagulating factor and immunoglobulin of human origin;";

(b) after the definition of "capital fee", there shall be inserted the following–

> ""change of ownership application" means an application for a product licence for a medicinal product in respect of which a person other than the applicant is already the holder of a product licence and which–
>
> (a) includes a statement to the effect that that other person intends to cease selling or supplying that product pursuant to that licence;
>
> (b) is signed by or on behalf of that other person, as well as by or on behalf of the applicant; and
>
> (c) except for the name and address of the applicant and particulars in relation to the labelling of the product, contains or is accompanied by, particulars which are in all material respects identical to the particulars referred to in the product licence already held by that other person;
>
> "immunological product" means any medicinal product which is a vaccine, toxin, serum or an allergen product;";

(c) after the definition of "product licence (parallel import)", there shall be inserted the following–

> ""radiopharmaceutical" means any medicinal product which, when ready for use, contains one or more radioactive isotopes which are included for a medicinal purpose;".

(3) In paragraph (2), for "Parts I and II", there shall be substituted "Part I".

Insertion of Part IIIA into the principal Regulations

4. After Part III of the principal Regulations (capital fees for applications for variations of licences or certificates and for associated inspections), there shall be inserted the following–

(**4**) S.I. 1991/1474.

"PART IIIA

CAPITAL FEES FOR RENEWALS OF CERTAIN PRODUCT LICENCES

Fees payable

9A.—(1) In connection with an application for the renewal of a product licence in respect of a blood product, an immunological product or a radiopharmaceutical, in respect of which a notice has been served under section 24(1A) of the Act, there shall be payable by the applicant, subject to paragraphs (2) and (3) and to regulation 19, a fee of £5,000.

(2) Where the application is for the renewal of a product licence granted on an application which was accompanied by–

(a) reports, each drawn up and signed by an expert having the necessary technical or professional qualifications in accordance with Article 2 of Council Directive 75/319/EEC(**5**); and

(b) a summary of product characteristics in accordance with Article 4a of Council Directive 65/65/EEC(**6**);

the fee payable under paragraph (1), subject to paragraph (3), shall be £2,000.

(3) Where an application for the renewal of a product licence referred to in paragraph (1) is in respect of more than one such licence each relating to a medicinal product containing the same active ingredient or combination of ingredients, the fee payable shall be–

(a) in connection with the first application considered by the licensing authority, the appropriate amount specified in paragraphs (1) or (2) above;

(b) in connection with each additional application relating to a different strength of active ingredient or a different combination of ingredients and where no further medical, scientific or pharmaceutical assessment is required, £1,000.

(4) In this Part of these Regulations, "active ingredient" shall have the same meaning as in Schedule 1.".

Amendment of regulation 12 of the principal Regulations

5. In regulation 12 of the principal Regulations (renewals in terms which are not identical to the existing certificate or licence), after the words "renewal of a certificate or licence", there shall be inserted the words ", other than a licence in respect of which a fee is payable under Part IIIA of these Regulations,".

Amendment of regulation 14 of the principal Regulations

6.—(1) Regulation 14 of the principal Regulations (periodic fees for licences) shall be amended in accordance with the following paragraphs of this regulation.

(2) In paragraph (1), for "(2)and (4)", there shall be substituted "(2), (4) and (5)".

(3) At the end of paragraph (3), there shall be added the words "and Part II of that Schedule shall have effect in relation to periodic fees.".

(4) At the end of paragraph (4), there shall be added the words– "except where that licence was granted pursuant to a change of ownership application and a periodic fee has not been paid in respect of that licence fee period in connection with the holding of a licence for the medicinal product to which the licence relates.".

(**5**) OJ No. L147, 9.6.1975, p.13.
(**6**) OJ No. 22, 9.2.1965, p.369/65, as inserted by Council Directive 83/570/EEC OJ No. L332, 28.11.1983.

(5) After paragraph (4), there shall be inserted the following paragraph–

"(5) Notwithstanding that a licence has neither expired nor been revoked, it shall be treated for the purposes of this regulation as not being in force during any part of a licence fee period if–

(a) not less than three months before the commencement of that period, the holder of that licence has given written notice to the licensing authority indicating that he wishes the licence to cease to have effect before the commencement of that period; and

(b) no products are sold, supplied or manufactured pursuant to that licence within the licence fee period.".

Amendment of regulation 16 of the principal Regulations

7.—(1) Regulation 16 of the principal Regulations (time for payment of capital fees in connection with applications or inspections), shall be amended in accordance with the following paragraphs of this regulation.

(2) In paragraph (1), for "paragraph (2)" there shall be substituted "paragraphs (1A) and (2)".

(3) After paragraph (1), there shall be inserted the following paragraph–

"(1A) Subject to regulations 17 and 19, in connection with an application for renewal of a product licence referred to in regulation 9A and in respect of which a fee is payable under paragraph (1) of that regulation, the capital fee shall, if the applicant so requests in writing, be payable–

(a) as to 25% of the fee payable on the date on which the application for renewal is made; and

(b) as to the remaining 75%, 6 months after that date or within 30 days following written notice from the licensing authority that the application has been determined, whichever shall be the earlier.".

Amendment of Schedule 1 to the principal Regulations

8.—(1) Schedule 1 to the principal Regulations (capital fees for applications for, and variations to, licences and certificates), shall be amended in accordance with the following paragraphs of this regulation.

(2) In paragraph 1 of Part I–

(a) for head (iv) of sub-paragraph (n) of the definition of "complex application", there shall be substituted the following–

"(iv) a change in two or more of that product's excipients which significantly affects the pharmaceutical or the therapeutic properties of that product; or";

(b) after that head (iv) there shall be inserted the following–

"(v) a change in the chemical form of that product's active ingredient.";

(c) for the definition of "standard application" there shall be substituted–

""standard application" means any application for a product licence which is not a major, complex, simple or change of ownership application or an application for a product licence (parallel import).";

(3) After the entries numbered 5 in Columns 1 and 2 of the Table in paragraph 1 of Part II there shall be inserted in Columns 1 and 2 respectively the following:–

"**6.** Change of ownership application	**6.**	£1,200".

(4) In paragraph 2 of Part II (capital fees for applications for licences and certificates), for the words "to which Part II of the Act applies by virtue of" there shall be substituted the words "described in paragraph 3 of the Schedule to".

Amendment of Schedule 2 to the principal Regulations

9.—(1) Schedule 2 to the principal Regulations (fees for inspections), shall be amended in accordance with the following paragraphs of this regulation.

(2) In paragraph 2 (fees)–

(a) for "paragraphs 3 to 5,", there shall be substituted "paragraphs 2A to 5,";

(b) in sub-paragraph (b), after the words "such products" there shall be inserted the words–

"except where the site inspected is concerned solely with the sterilisation of medicinal products which have been manufactured elsewhere,".

(3) After paragraph 2, there shall be inserted the following paragraph–

"**2A.**—(1) Where any inspection at a site would be a supersite inspection and that site consists of two or more separate manufacturing operations on different parts of the site, an inspection may, pursuant to a request in writing from the applicant, or as the case may be, the licence holder, relate to one or more manufacturing facilities at that site.

(2) An inspection referred to in sub-paragraph (1) shall be categorised in accordance with the number of relevant persons employed in each manufacturing operation which is inspected as if that operation constituted the entire site and the fee payable for that inspection shall be the appropriate fee specified for that category in paragraph 2, or if more than one manufacturing operation is inspected, the aggregate of the appropriate fees shall be payable.".

Amendment of Schedule 3 to the principal Regulations

10.—(1) Schedule 3 to the principal Regulations (periodic fees for licences), shall be amended in accordance with the following paragraphs of this regulation.

(2) In paragraph 1 of Part I, in the definition of "anthroposophic product", after the words "medicine which is", there shall be inserted the word "sold".

(3) In sub-paragraphs (1) and (2) of paragraph 4 of Part III, for the words "until and including the relevant licence fee period during which falls the fifth anniversary of the granting of the licence." there shall be substituted in each case–

"(a) where that licence was granted before 1st April 1991, until and including the relevant licence fee period during which falls the fifth anniversary of the granting of the licence; and

(b) where that licence was granted on or after 1st April 1991, until and including the relevant licence fee period during which falls the fourth anniversary of the granting of the licence.".

(4) For paragraph 2 of Part IV there shall be substituted the following–

"**2.** Licences held in respect of homoeopathic or anthroposophic products which are–

(a) two or more attenuations of the same mother tincture or other solution or of the same trituration; or

(b) two or more attenuations of a particular combination of mother tinctures, other solutions or triturations.".

Amendment of Schedule 4 to the principal Regulations

11. After paragraph 2 of Schedule 4 to the principal Regulations (time for payment of capital fees-applications made by small companies) there shall be inserted the following paragraph–

"**2A.** In connection with an application for renewal of a product licence to which regulation 9A applies and in respect of which a fee is payable under paragraph (1) of that regulation, the fee shall, if the applicant so requests in writing, be payable as to 25% of the fee payable on the date on which the application for renewal is made and as to the remaining 75%, 12 months after that date or within 30 days following written notice from the licensing authority that the application has been determined, whichever shall be the earlier.".

Signed by authority of the Secretary of State for Health.

Virginia Bottomley
Minister of State
12th March 1992 Department of Health

David Hunt
12th March 1992 Secretary of State for Wales

Michael Forsyth
12th March 1992 Minister of State for Scotland

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on

L.S.

Derek Andrews
Permanent Secretary, Ministry of Agriculture,
12th March 1992. 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
12th March 1992. Permanent Secretary

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

L.S.

W. J. Hodges
12th March 1992. Permanent Secretary

We consent,

Sidney Chapman
Irvine Patnick
Two of the Lords Commissioners of Her
12th March 1992. Majesty's Treasury

SCHEDULE Regulation 2

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)		£150	£160
Regulation 6(1)(b)		£75	£80
Regulation 6(1)(c)(i)		£75	£80
Regulation 6(1)(c)(ii)		£15	£16
Regulation 10–	renewal of certificates	£3,500	£3,700
Regulation 11–	renewal of certain manufacturers' licences	£80	£85
Schedule 1–			
Part II–	fees for applications for licences and clinical trial certificates		
Column 2 of the Table to paragraph 1–			
entry 1(a)		£17,000	£17,850
entry 1(b)		£92,000	£97,500
entry 2		£17,000	£17,800
entry 3		£7,000	£7,385
entry 4		£2,000	£2,090
entry 5		£1,750	£1,850
paragraph 6(1)(a)		£80	£85
paragraph 6(1)(b)		£1,400	£1,500
paragraph 7(1)		£750	£790
paragraph 7(2)		£400	£425
paragraph 8		£17,000	£17,500
Part III–	fees for applications for variations of licences and clinical trial certificates		
paragraph 1(a)		£8,500	£8,925
paragraph 1(b)		£280	£300

Column (1) Provision in the principal Regulations	Column (2) Subject matter	Column (3) Old amount	Column (4) New amount
paragraph 4		£80	£85
paragraph 5(b)		£200	£210
paragraph 9		£280	£290
Schedule 2–	fees for inspections		
paragraph 2(a)(i)		£1,350	£1,445
paragraph 2(a)(ii)		£2,700	£2,970
paragraph 2(a)(iii)		£5,100	£5,610
paragraph 2(a)(iv)		£10,200	£10,915
paragraph 2(b)(i)		£1,500	£1,610
paragraph 2(b)(ii)		£5,500	£5,940
paragraph 2(b)(iii)		£8,500	£9,350
paragraph 2(b)(iv)		£17,000	£18,190
paragraph 2(c)(i)		£500	£530
paragraph 2(c)(ii)		£1,350	£1,485
paragraph 2(c)(iii)		£2,700	£2,835
paragraph 2(c)(iv)		£5,400	£5,670
paragraph 2(d)		£100	£105
paragraph 4(a)		£650	£700
paragraph 4(b)		£300	£320
paragraph 4(c)		£300	£320
Schedule 3–			
Part III–	periodic fees for licences		
Column 2 of the Table to paragraph 1–			
entry 1		£10,000	£10,550
entry 2(a)		£5,000	£5,275
entry 2(b)(i)		£900	£950
entry 2(b)(ii)		£450	£475
entry 2(b)(iii)		£150	£160
entry 2(c)(i)		£450	£475
entry 2(c)(ii)		£225	£240
entry 2(c)(iii)		£100	£105
entry 2(d)(i)		£200	£210

Column (1) Provision in the principal Regulations	Column (2) Subject matter	Column (3) Old amount	Column (4) New amount
entry 2(d)(ii)		£100	£105
entry 2(d)(iii)		£75	£80
entry 2(e)		£50	£53
entry 2(f)		£25	£27
paragraph 2(a)		£250	£265
paragraph 2(b)		£125	£130
paragraph 2(c)		£80	£85
paragraph 3(a)		£3,000	£3,165
paragraph 3(b)		£5,000	£5,275
paragraph 7		£200	£210
paragraph 8(1)		£125	£130
paragraph 8(2)		£75	£80

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Products for Human Use– Fees) Regulations 1991 which prescribe fees in connection with applications and inspections relating to licences and certificates granted under the Medicines Act 1968 and also prescribe periodic fees in connection with the holding of such licences, insofar as they apply to medicinal products for human use only.

These Regulations (regulation 2 and the Schedule) increase (with a few minor exceptions where the fees have remained the same) the fees payable for applications for the grant of product licences, manufacturers' licences, wholesale dealers' licences, clinical trial certificates and export certificates, for variations of such licences or certificates, for the renewal of certain manufacturers' licences and clinical trial certificates and periodic fees in connection with the holding of licences. They also increase the fees payable in respect of inspections of sites carried out in connection with applications for, or during the currency of, such licences. The new fees represent an overall average increase of 5.5%.

These Regulations also provide for special fees to be payable in connection with applications for renewal of certain product licences. This provision is made in connection with the implementation of Council Directives–

89/342/EEC relating to immunological products (OJNo. L142, 25.5.1989, p.14);

89/343/EEC relating to radiopharmaceuticals (OJ No. L142 25.5.1989, p.16); and

89/381/EEC relating to medicinal products derived from human blood or human plasma (OJ No. L181, 28.6.1989, p.44).

These Directives extend the scope of Council Directives 65/65/EEC (OJ No. 22, 9.2.1965, p.369/65) and 75/319/EEC (OJ No. L147, 9.6.1975, p.13) on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products to cover such products which had previously been excluded by Article 34 of Council Directive 75/319/EEC (regulations 3(2), 4 and 5).

Three scales of fees are provided for in connection with these applications. The lowest scale relates to applications accompanying other applications which are for different strengths of a medicinal product and where no medical, scientific or pharmaceutical assessment is required. The next scale applies where the application for the original product licence was accompanied by an Expert's Report and a Summary of Product Characteristics. The regulations provide for the higher fees to be payable in all other cases and provide that these may be payable in two instalments over six months (regulation 7). Small companies are given an extra six months in which to pay these higher fees (regulation 11).

These Regulations also provide for a lower rate of fee to be payable in respect of applications for product licences which may be made in circumstances where a product licence already exists in respect of a medicinal product and an application is made by a different person in identical terms to that relating to the existing product licence (regulations 3(2)(b), 8(2)(c) and (3)), and make special provision for periodic fees for the first licence fee period of the new licence (regulation 6(4)).

It is also provided that where the licensing authority receives a request to cancel a licence not less than three months before the commencement of a licence fee period, for the purpose of periodic fees, that licence shall not be considered to be in force at the beginning of that period (regulation 6(2) and (5)).

These Regulations also make other minor amendments relating to, interpretation provisions (regulations 3(3) and 6(3)), complex applications for product licences (regulation 8(2)(a) and (b)), certain surgical materials (regulation 8(4)), inspections of sites where only sterilisation of products manufactured elsewhere takes place (regulation 9(2)), inspections of especially large sites (regulation 9(3)), homoeopathic and anthroposophic products (regulation 10(2) and (4)), and the payment of periodic fees for new active substances or derivatives of new active substances (regulation 10(3)).