STATUTORY INSTRUMENTS

1994 No. 696

MEDICINES

The Medicines (Products for Human Use —Fees) Amendment Regulations 1994

Made - - - -	*10th March 1994*
Laid before Parliament	*11th March 1994*
Coming into force - -	*1st April 1994*

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, 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, with the consent of the Treasury, 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 1994 and shall come into force on 1st April 1994.

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

(**1**) 1971 c. 69; section 1(1) was 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) and specified provisions of that Act, including section 129(2), (3)(c), (5) and (6), have effect as if any reference to that Act in those provisions included a reference to section 1 of the 1971 Act.The expression "the Ministers" is defined in section 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 Act.

(**4**) S.I. 1991/1474; the relevant amending instrument is S.I. 1992/756.

Amendment of 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 that Schedule (the subject matter of which is indicated in Column 2 of that Schedule), there shall be substituted the amount specified in relation to it in Column 4 of that Schedule.

Amendment of regulation 2 of the principal Regulations

3. In paragraph (1) of regulation 2 of the principal Regulations (interpretation)—

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

> ""the Applications Regulations" means the Medicines (Applications for the Grant of Product Licences—Products for Human Use) Regulations 1993;"(**5**); and

(b) the definition of "radiopharmaceutical" shall be omitted.

Amendment of regulation 5 of the principal Regulations

4. In regulation 5 of the principal Regulations (inspections in connection with multiple applications for licences) after "medicinal product" there shall be inserted ", or for the preparation of a substance which is to be used in the manufacture of an immunological product or a blood product,".

Amendment of regulation 8 of the principal Regulations

5. In regulation 8 of the principal Regulations (inspections in connection with multiple applications for variations of licences) after "medicinal product" there shall be inserted ", or for the preparation of a substance which is to be used in the manufacture of an immunological product or a blood product,".

Amendment of regulation 14 of the principal Regulations

6. For paragraph (4) of regulation 14 of the principal Regulations (periodic fees for licences) there shall be substituted the following paragraph—

> "(4) No periodic fee shall be payable in respect of the licence fee period during which a licence is first granted except where that licence was granted pursuant to—
>
> (a) a change of ownership application; or
>
> (b) an application, made no later than three months after the expiry of a licence, which is for a licence containing identical provisions to those contained in the expired licence and which is made by the person who held the expired licence,
>
> and, in each case, 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.".

Amendment of Schedule 1 to the principal Regulations

7.—(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—

(**5**) S.I. 1993/2538.

(a) in the definition of "active ingredient", the word "therapeutic" shall be omitted and after the word "efficacy" there shall be inserted "(whether therapeutic, diagnostic or otherwise)";

(b) in the definition of "complex application"—

(i) for "(a) to (n)" there shall be substituted "(a) to (q)";

(ii) at the end of sub-paragraph (m), "or" shall be omitted;

(iii) after sub-paragraph (n), the following paragraphs shall be inserted—

"(o) the application is for the grant of a product licence for a medicinal product which is to be administered by way of a metered dose inhaler;

(p) the application is for the grant of a product licence for a medicinal product which is in a powdered form and is to be administered by way of inhalation; or

(q) the application relates to a medicinal product—

(i) which is administered to the site of action by a different route from that used in relation to any other medicinal product which contains the same active ingredient as the product in question and,

(ii) in respect of that other product, a product licence (other than a product licence of right) has previously been granted in the United Kingdom.";

(c) in the definition of "simple application"—

(i) after the word "means" there shall be inserted "(a)",

(ii) at the end there shall be inserted—

"or (b) an application, made no later than three months after the expiry of a product licence, which is for a product licence containing identical provisions to those contained in the expired licence and which is made by the person who held the expired licence;".

(3) In Part II (capital fees for applications for licences and certificates)—

(a) in Column 1 of the Table in paragraph 1, in entry 1(a)(i) for "paragraph 5 of Chapter III of Part 3 of the Annex to Council Directive 75/318/EEC(a)" there shall be substituted "paragraph 5 of Schedule 2 to the Applications Regulations";

(b) in paragraph 4—

(i) in sub-paragraph (1), in the definition of "primary applicant", before "; and" there shall be inserted "or that party to a joint development who first makes an application for a product licence relating to a different dosage form or strength of that new active ingredient",

(ii) at the beginning of sub-paragraph (2) there shall be inserted "Subject to sub-paragraph (3) below,",

(iii) after sub-paragraph (2) there shall be inserted the following sub-paragraph—

"(3) Where a primary applicant and one or more secondary applicants each submit an application for a product licence to the licensing authority, both or all of which applications relate to identical dosage forms and strengths of the medicinal product to which the joint development relates—

(a) where the amount payable by the primary applicant is that in respect of a complex application, the fee payable under regulation 4(a) by each secondary applicant shall be that in respect of a standard application under paragraph 1 above;

(b) where the amount payable by the primary applicant is that in respect of a standard application, the fee payable under regulation 4(a) by each secondary applicant shall be that in respect of a simple application under paragraph 1 above.";

(c) for sub-paragraph (2) of paragraph 7, there shall be substituted—

"(2) The fee payable under regulation 4(a) shall be £500 where an application for a wholesale dealer's licence—

(a) relates to anything done in a registered pharmacy by or under the supervision of a pharmacist and amounting to wholesale dealing, where such dealing constitutes no more than 15% of the total turnover of the saleof licensed medicinal products carried on at that pharmacy; or

(b) does not relate to anything done in a registered pharmacy but where the applicant's total turnover of the sale by way of wholesale dealing of licensed medicinal products does not exceed £30,000.".

(4) In Part III (capital fees for variations of licences and certificates)—

(a) in paragraph 1—

(i) the word "and" after sub-paragraph (a) shall be omitted,

(ii) after sub-paragraph (a) there shall be inserted—

"(aa) in the case of an application relating to a product licence (parallel import) to which paragraph 3 or 4 does not apply, £325; and";

(b) in paragraph 2—

(i) at the beginning, there shall be inserted "Subject to paragraph 2A,",

(ii) for "paragraph 5 of Chapter III of Part 3 of the Annex to Council Directive 75/318/EEC" there shall be substituted "paragraph 5 of Schedule 2 to the Application Regulations";

(c) after paragraph 2, there shall be inserted the following paragraph—

"**2A.** Paragraph 2 shall not apply where the first application for variation of the product licence relates to a particular therapeutic area in respect of which the applicant would be entitled (had he not already held a product licence) to apply for a product licence without, under paragraph 5 of Schedule 2 to the Applications Regulations, having to provide the results of tests or trials in accordance with paragraph 8 of Schedule 1 to those Regulations".

Amendment of Schedule 2 to the principal Regulations

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

(2) After sub-paragraph (2) of paragraph 1 the following sub-paragraph shall be inserted—

"(3) Any reference in sub-paragraphs (1) and (2) above to the manufacture or assembly of medicinal products includes a reference to the preparation of substances which are used in the manufacture of an immunological product or a blood product.".

(3) In sub-paragraph (1) of paragraph 2A, for "facilities" there shall be substituted "operations".

Amendment of Schedule 3 to the principal Regulations

9.—(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 Part I (interpretation), in the definition of "limited use drug"in paragraph 1, for the words "paragraph 5 of Chapter III of Part 3 of the Annex to the Council Directive 75/318/EEC" there shall be substituted "paragraph 5 of Schedule 2 to the Applications Regulations".

(3) In Part III (periodic fees for licences)—

(a) in paragraph 4, for sub-paragraph (4) there shall be substituted the following sub-paragraph—

"(4) Where a product licence is surrendered and at the same time another product licence held by the licence holder is varied so as to include in that other licence the provisions of the surrendered licence—

(a) where the varied licence relates to a new active substance, the fee payable in respect of the varied licence shall, for each fee period mentioned in sub-paragraph (1) above, be that specified at entry 1 of the Table in paragraph 1;

(b) in all other cases, the fee payable in respect of the varied licence shall, for each fee period mentioned in sub-paragraph (3) above, be that specified at entry 2(a) of that Table.";

(b) in sub-paragraph 2(a) of paragraph 8, after "that pharmacy" there shall be inserted "or, where the licence does not relate to anything done in a registered pharmacy, where the licence holder's total turnover of the sale by way of wholesale dealing of licensed medicinal products does not exceed £30,000.".

Amendment of Schedule 5 to the principal Regulations

10. In paragraph 2 of Schedule 5 to the principal Regulations (waiver, reduction or refund of capital fees)—

(a) in sub-paragraph (1), for "sub-paragraph (2)," there shall be substituted "sub-paragraphs (1A) and (2) below,";

(b) after sub-paragraph (1) the following sub-paragraph shall be inserted—

"(1A) Where paragraph (1)(a) applies and the fee otherwise payable under regulation 4(a), 7(a) or 10 exceeds £15,000, the amount of the refund or the amount waived shall be the difference between that fee and £1,500, rather than 90% of that fee.".

Revocation

11. The following provisions shall be revoked—

(a) Part IIIA (that is, regulation 9A) (capital fees for renewals of certain product licences) of, and paragraph 2A of Schedule 4 (time for payment of capital fees—applications made by small companies) to, the principal Regulations, and

(b) regulations 4 (insertion of Part IIIA into the principal Regulations) and 11 (amendment of Schedule 4 to the principal Regulations) of the Medicines (Products for Human Use-Fees) Regulations 1992(**6**).

(**6**) S.I. 1992/756.

Signed by authority of the Secretary of State for Health

Tom Sackville
Parliamentary Under Secretary of State,
4th March 1994 Department of Health

John Redwood
7th March 1994 Secretary of State for Wales

Fraser of Carmyllie
9th March 1994 Minister of State, The Scottish Office

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

L.S.

Gillian Shephard
7th March 1994. Minister of Agriculture, 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
7th March 1994. Permanent Secretary

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

L.S.

J. Murray
7th March 1994. Permanent Secretary

We consent,

Irvine Patnick
Tim Wood
Two of the Lords Commissioners of Her Majesty's Treasury

10th March 1994

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)		£160	£140
Regulation 6(1)(b)		£80	£70
Regulation 6(1)(c)(i)		£80	£70
Regulation 10—	renewals of clinical trial certificates	£3,700	£3,210
Regulation 11—	renewals of certain manufacturers' licences	£85	£90
Schedule 1—			
Part II—	capital fees for applications for licences and certificates		
Column 2 of the Table to paragraph 1—			
entry 1(a)		£17,850	£21,225
entry 1(b)		£97,500	£84,650
entry 2		£17,800	£15,500
entry 3		£7,385	£6,400
entry 4		£2,090	£1,800
entry 5		£1,850	£2,000
entry 6		£1,200	£1,050
paragraph 2		£250	£300
paragraph 6(1)(a)		£85	£100
paragraph 6(1)(b)		£1,500	£1,780
paragraph 7(1)		£790	£820
paragraph 8		£17,500	£15,225
Part III—	capital fees for applications for variations of licences and certificates		
paragraph 1(a)		£8,925	£9,225
paragraph 1(b)		£300	£270

Column 1 Provision in the principal Regulations	Column 2 Subject matter	Column 3 Old amount	Column 4 New amount
paragraph 4		£85	£100
paragraph 5(a)		£80	£95
paragraph 5(b)		£210	£190
paragraph 6		£80	£95
paragraph 7		£200	£220
paragraph 8		£80	£95
paragraph 9		£290	£250
paragraph 10		£80	£95
Schedule 2—	fees for inspections		
paragraph 2(a)(i)		£1,445	£1,645
paragraph 2(a)(ii)		£2,970	£3,100
paragraph 2(a)(iii)		£5,610	£5,000
paragraph 2(a)(iv)		£10,915	£9,500
paragraph 2(b)(i)		£1,610	£1,830
paragraph 2(b)(ii)		£5,940	£5,150
paragraph 2(b)(iii)		£9,350	£8,300
paragraph 2(b)(iv)		£18,190	£15,800
paragraph 2(c)(i)		£530	£630
paragraph 2(c)(ii)		£1,485	£1,770
paragraph 2(c)(iii)		£2,835	£2,935
paragraph 2(c)(iv)		£5,670	£5,500
paragraph 2(d)	£105	£120	
paragraph 4(a)		£700	£725
paragraph 4(b)		£320	£330
paragraph 4(c)		£320	£330
Schedule 3—			
Part III—	periodic fees for licences		
Column 2 of the Table to paragraph 1—			
entry 1		£10,550	£11,900
entry 2(a)		£5,275	£5,950
entry 2(b)(i)		£950	£1,075
entry 2(b)(ii)		£475	£535

Column 1 Provision in the principal Regulations	Column 2 Subject matter	Column 3 Old amount	Column 4 New amount
entry 2(b)(iii)		£160	£180
entry 2(c)(i)		£475	£535
entry 2(c)(ii)		£240	£270
entry 2(c)(iii)		£105	£120
entry 2(d)(i)		£210	£240
entry 2(d)(ii)		£105	£120
entry 2(d)(iii)		£80	£90
entry 2(e)		£53	£60
entry 2(f)		£27	£30
paragraph 2(a)		£265	£300
paragraph 2(b)		£130	£145
paragraph 2(c)		£85	£95
paragraph 3(a)		£3,165	£3,575
paragraph 3(b)		£5,275	£5,950
paragraph 7		£210	£235
paragraph 8(1)		£130	£145
paragraph 8(2)		£80	£90

EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations further amend the Medicines (Products for Human Use Fees) Regulations 1991 ("the principal Regulations"), which prescribe fees in connection with applications and inspections relating to licences and certificates granted under the Medicines Act 1968 and 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) vary most of 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 vary the fees payable in respect of inspections of sites carried out in connection with applications for, or during the currency of, such licences. The result of these variations is that capital fees have been reduced by an overall average of 10% and periodic fees have

been increased by an overall average of 13%. A copy of the Compliance Cost Assessment can be obtained from the House of Commons Library.

These Regulations also make a number of miscellaneous amendments:

— they provide for fees to be payable in relation to inspection of sites used in the preparation of biological intermediate prducts (regulations 4, 5 and 8(2));

— they provide for a concessionary fee where applications for product licences are received within three months of the expiry of a product licence for the same product and ensure that liability for a periodic fee remains as if the original licence had not expired (regulations 6 and 7(2)(c));

— they amend the definition of "active ingredient" (regulation 7(2)(a)) and insert new categories in the definition of "complex application" in Part I of Schedule 1 to the principal Regulations (regulation 7(2)(b));

— they amend paragraph 4 of Part II of Schedule 1 to the principal Regulations in respect of the charging of fees relating to applications for product licences which form a joint development between two or more applicants (regulation 7(3)(b));

— they increase the concessionary rate (in paragraph 7(2) of Part II of Schedule 1 and paragraph 8(2)(a) of Part III of Schedule 3 to the principal Regulations) applying to certain applicants for and holders of wholesale dealer's licences (regulations 7(3)(c) and 9(3)(b));

— they substitute for references to Council Directive 75/318/EEC (OJNo. L147, 9.6.1975, p.1), references to the Medicines (Applications for the Grant of Product Licences Products for Human Use) Regulations 1993 (S. I.1993/2538) and make consequential amendments (regulations 3(a), 7(3)(a), 7(4)(a)(ii) and 9(2)); they also disapply paragraph 2 of Part III of Schedule 1 to the principal Regulations which required the levying of a higher fee for an application for the variation of a licence granted under this provision in specified circumstances (regulation 7(4)(a)(i) and (b));

— they clarify paragraph 4 of Part III of Schedule 3 to the principal Regulations (liability for periodic fees for product licences relating to new active substances) (regulation 9(3)(a));

— they reduce the liability for the standard charge on withdrawal of an application for a product licence in specified circumstances (regulation 10);

— they revoke Part IIIA of, and paragraph 2A of Schedule 4 to, the principal Regulations (fees to be payable on renewal of certain product licences) and make consequential amendments (regulations 3(b) and 11);

— they effect a drafting improvement in Schedule 2 to the principal Regulations (regulation 8(3)).