STATUTORY INSTRUMENTS

1992 No. 756

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

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.

(2) In these Regulations, "the principal Regulations" means the Medicines (Products for Human Use– Fees) Regulations 1991(**1**).

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;

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

"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–

"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(**2**); and

(b) a summary of product characteristics in accordance with Article 4a of Council Directive 65/65/EEC(**3**);

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.".

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

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) 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, Fisheries and Food

12th March 1992.

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

L.S.

F. A. Elliott
Permanent Secretary

12th March 1992.

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

L.S.

W. J. Hodges
Permanent Secretary

12th March 1992.

We consent,

Sidney Chapman
Irvine Patnick
Two of the Lords Commissioners of Her Majesty's Treasury

12th March 1992.