## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Medicines (Fees Relating to Medicinal Products for Human Use) Regulations 1989 which prescribe fees in connection with applications and inspections relating to licences and certificates granted under the Medicines Act 1968 so far as they apply to medicinal products for human use only.

These Regulations increase fees payable for application for the grant of product licences, manufacturers' licences, wholesale dealers' licences, clinical trial certificates and export certificates (regulations 5, 6 and 17), for variations of such licences or certificates (regulations 7, 8 and 17) and for their renewal (regulations 17 and 18). 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 or certificates (regulation 20).

These Regulations make various other amendments as follows:–

– they make permanent a temporary provision for a reduced fee relating to applications for product licences for certain surgical materials (regulations 2, 15 and 17(c));

– they extend the definition of complex application and alter the distinction between complex, simple and standard applications, which is relevant for determining fees for applications for the grant, variation and renewal of licences (regulation 16);

– they extend the provisions on waiver of fees (regulation 22);

– they provide for the fee payable where applications for renewal are submitted more than four months before a licence is due to expire (regulations 3 and 14(b));

– they provide for inspection fees to be equally divided between applicants who name the same site of manufacture (regulations 4, 7, 11 and 13);

– they make provision for the fee payable in respect of applications made at the same time to renew product licences for medicinal products which are identical except for their strength (regulation 19(b));

– they make provision for the fee payable in respect of applications to vary licences where such variations are identical (regulation 18(e)) or where no separate assessment is required (regulation 10);

– they provide for fees which are payable by small companies as defined by these Regulations, to be paid by instalments (regulations 14(c), 21 and the Schedule).

*W. J. Hodges*
Permanent Secretary

We consent,

*Stephen Dorrell*
*John M. Taylor*
8th February 1990. Two of the Lords Commissioners of Her Majesty's Treasury

## SCHEDULE

Regulation 21

## NEW SCHEDULE 2A TO THE PRINCIPAL REGULATIONS

"SCHEDULE 2A

Regulation 15(A)1

### TIME FOR PAYMENT OF FEES – APPLICATIONS MADE BY SMALL COMPANIES

**1.** In connection with a major application for a product licence for which the fee payable is that specified in entry 1(b) of the Table in paragraph 1 of Part II of Schedule 1 to these Regulations, the fee payable under regulation 3(a) of these Regulations shall, if the applicant so requests in writing, by payable as to 25% at the time of the application and as to 75% within 30 days following written notice from the licensing authority that the application has been determined.

**2.** In connection with an application to which paragraph 3 of Part II of Schedule 1 to these Regulations applies, the fee payable under regulation 3(a) of these Regulations shall, if the applicant so requests in writing, be payable–

(a) as to 50% of the aggregate payable in accordance with that paragraph at the time of the application;

(b) as to 50% of that aggregate within 30 days following written notice from the licensing authority that the application has been determined.

**3.** In connection with an application for a manufacturer's licence or a wholesale dealer's licence, the fee payable under regulation 3(a) of these Regulations shall, if the applicant so requests in writing, be payable as to 50% at the time of the application and as to 50% 12 months after that time.

**4.** In connection with an application for renewal of a product licence made by a holder of a licence 40% or more of whose product licences are due to expire in any one year (beginning on 1st January), the fee payable under regulation 10(a) of these Regulations shall, if the holder of the licence so requests in writing, be payable–

(a) as to 20% at the time of the application;

(b) as to the remaining 80% in four equal instalments payable respectively 1, 2, 3 and 4 years after that time.

**5.** In connection with an application for a product licence, manufacturer's licence or wholesale dealer's licence, the fee payable in respect of an inspection at any site other than one named as a possible site for manufacture of a medicinal product by three or more applicants shall, if the applicant so requests in writing, be payable as to 50% within the period of 14 days referred to in regulation 15(3) and as to 50% 12 months after that date.

**6.** In this Schedule a reference to an application is to an application made by or on behalf of a small company."

**Amendment of Schedule 3 to the principal Regulations**

**22.** In Schedule 3 to the principal Regulations (waiver, reduction or refund of fees)–

(a) in paragraphs 2(1) and 2(2)–

(i) after "clinical trial certificate" there shall be inserted in each case "or for a variation to or for a renewal of a product licence"; and

(ii) for "3(a) or 4" there shall be substituted in each case "3(a), 4, 6 or 10";

(b) after paragraph 4 there shall be inserted the following paragraph–

"**5.** The fee payable in respect of each such application shall be waived where–

(a) a product licence (parallel import) relates to a medicinal product in respect of which a separate marketing authorisation has been granted pursuant to the provisions of Council Directive 65/65/EEC(**a**) in more than one Member State of the European Economic Community; and

(b) those marketing authorisations are indicated on the product licence (parallel import) as having been validly granted in those Member States; and

(c) the holder of that licence applies for the grant of a separate product licence (parallel import) in respect of each marketing authorisation which has been granted and so indicated.".

8th February 1990

*Virginia Bottomley*
Minister of State Department of Health

7th February 1990

*I. Grist*
Parliamentary Under Secretary of State, Welsh Office

7th February 1990

*M. B. Forsyth*
Parliamentary Under Secretary of State, Scottish Office

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 7th February 1990.

*John Selwyn Gummer*
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 7th February 1990.

*F. A. Elliot*
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland 7th February 1990.

(**a**) O.J. No. 22, 9.2. 1965, p.369/65, as amended by Council Directives 75/319/EEC O.J. No. L147, 9.6. 1975, p.13, 83/570/EEC O.J. No. L332, 28.11. 1983, p.1, 87/21/EEC O.J. No. L15, 17.1. 1987, p.36 and 89/341/EEC O.J. No. L142, 25.5. 1989 p.11.

**"Identical variations**

**5.** Where more than one application (not being a complex application) is made at the same time for the variation of a product licence, a manufacturer's licence or a wholesale dealer's licence for medicinal products, where the applications are for identical variations the fee payable under regulation 6(a) of these Regulations–

(a) in connection with the first application considered by the licensing authority shall be the appropriate amount specified in this Part of this Schedule;

(b) in connection with each of the other applications shall be 50% of that amount.".

**Amendment of Part IV of Schedule 1 to the principal Regulations**

**19.** In Part IV of Schedule 1 to the principal Regulations (fees for applications for renewals of licences)–

(a) in paragraph 1–

(i) before the words "The fee payable under Regulation 10(a)", there shall be inserted the words "Subject to the provisions of paragraph 1A below";

(ii) in sub-paragraph (a) for "£100" there shall be substituted "£170";

(iii) in sub-paragraph (b) for "£500" there shall be substituted "£850";

(iv) in sub-paragraph (c) for "£750" there shall be substituted "£1,275";

(v) in sub-paragraph (d) for "£500" there shall be substituted "£850";

(b) after paragraph 1 there shall be inserted–

"**1A.** Where more than one application is made at the same time for the renewal of a product licence for medicinal products which are identical except for their respective strengths, the fee payable under regulation 10(a) of these Regulations–

(a) in connection with the first application considered by the licensing authority shall be the appropriate amount specified in paragraph 1 of this Part of this Schedule;

(b) in connection with each of the other applications shall be 50% of that amount.";

(c) in paragraph 2–

(i) in sub-paragraph (a) for "£50" there shall be substituted "£85";

(ii) in sub-paragraph (b) for "£500" there shall be substituted "£850";

(d) in paragraph 3 for "£325" there shall be substituted "£550".

**Amendment of Schedule 2 to the principal Regulations**

**20.** In Schedule 2 to the principal Regulations (fees for inspections)–

(a) in paragraph 2–

(i) in sub-paragraph (a)(i) for "£750" there shall be substituted "£1,275";

(ii) in sub-paragraph (a)(ii) for "£1,500" there shall be substituted "£2,550";

(iii) in sub-paragraph (a)(iii) for "£3,000" there shall be substituted "£5,100";

(iv) in sub-paragraph (b)(i) for "£1,250" there shall be substituted "£2,125";

(v) in sub-paragraph (b)(ii) for "£2,500" there shall be substituted "£4,250";

(vi) in sub-paragraph (b)(iii) for "£5,000" there shall be substituted "£8,500";

(vii) in sub-paragraph (c)(i) for "£500" there shall be substituted "£850";

(viii) in sub-paragraph (c)(ii) for "£1,000" there shall be substituted "£1,700";

(ix) in sub-paragraph (c)(iii) for "£2,000" there shall be substituted "£3,400";

(x) in sub-paragraph (d) for "£50" there shall be substituted "£85";

(b) in paragraph 4(a) for "£650" there shall be substituted "£1,105" and in paragraph 4(b) for "£250" there shall be substituted "£425".

**Insertion of Schedule 2A in the principal Regulations**

**21.** After Schedule 2 to the principal Regulations there shall be inserted the Schedule 2A set out in the Schedule to these Regulations.

(n) is to vary a product licence and relates to a change in the formulation of the medicinal product comprising one or more of the following–

(i) a change in the quantity of that product's active ingredient;

(ii) a change which necessitates in-vivo bioavailability studies to be performed on that product;

(iii) a change in that product's preservative system; or

(iv) a change in two or more of that product's excipients other than to colours or substances which are present only in trace amounts in the finished product.";

(b) in the definition of "simple application", after the word "applies", there shall be inserted the following–

"other than one for a product licence for a medicinal product which is a new strength of a product in respect of which a product licence has previously been granted in the United Kingdom;".

**Amendment of Part II of Schedule 1 to the principal Regulations**

**17.** In Part II of Schedule 1 to the principal Regulations (fees for applications for licences)–

(a) in paragraph 1 for "Subject to paragraphs 2 and 3 below" there shall be substituted "Subject to paragraphs 1A, 2 and 3 below";

(b) in Column 2 of the Table in paragraph 1–

(i) for "£8,000" specified at entry 1(a) there shall be substituted "£13,600" and for "£40,000" specified at entry 1(b) there shall be substituted "£68,000";

(ii) for "£6,000" specified at entry 2 there shall be substituted "£10,200";

(iii) for "£3,000" specified at entry 3 there shall be substituted "£5,100";

(iv) for "£1,500" specified at entry 4 there shall be substituted "£2,550"; and

(v) for "£1,500" specified at entry 5(a) there shall be substituted "£2,550" and for "£1,000" specified at entry 5(b) there shall be substituted "£1,700";

(c) after paragraph 1 there shall be inserted the following paragraph–

"**1A.** Notwithstanding the provisions of paragraph 1 above, in the case of an article or substance to which Part II of the Medicines Act 1968 applies by virtue of the Medicines (Surgical Materials) Order 1971(**a**), the fee payable under these Regulations in respect of an application for a product licence made at the specific written invitation of the licensing authority shall be £250.";

(d) in paragraph 4–

(i) in sub-paragraph (1)(a) for "£50" there shall be substituted "£85";

(ii) in sub-paragraph (1)(b) for "£1,000" there shall be substituted "£1,700"; and

(e) in paragraph 5 for "£650" there shall be substituted "£1,105".

**Amendment of Part III of Schedule 1 to the principal Regulations**

**18.** In Part III of Schedule 1 to the principal Regulations (fees for applications for variations of licences)–

(a) in paragraph 1–

(i) for "paragraph 4 below" there shall be substituted "paragraphs 4 and 5 below";

(ii) in sub-paragraph (a) for "£1,250" there shall be substituted "£2,125"; and

(iii) in sub-paragraph (b) for "£175" there shall be substituted "£300";

(b) in paragraph 2(a) for "£50" there shall be substituted "£85" and in paragraph 2(b) for "£175" there shall be substituted "£300";

(c) in paragraph 3 for "£175" there shall be substituted "£300";

(d) in paragraph 4 for "£50" there shall be substituted "£85";

(e) after paragraph 4 there shall be inserted the following paragraph–

(**a**) S.I. 1971/1267.

**Amendment of regulation 15 of the principal Regulations**

**14.** Regulation 15 of the principal Regulations (time for payment of fees in connection with applications or inspections and refunds of such fees) shall be amended as follows–

(a) in regulation 15(1) for "Subject to paragraphs (2) and (3) below" there shall be substituted "Subject to paragraphs (2), (3), (4) and to regulation 15A below"; and

(b) after paragraph (3) there shall be inserted–

"(4) Where regulation 2A(2) of these Regulations applies, there shall be payable at the time of the application the amount payable in accordance with these Regulations as in force at that time and paragraph (2) above shall have effect as respects the fee properly payable in accordance with regulation 2A(2).";

(c) after paragraph (4) there shall be inserted the following Regulation–

**"Time for payment of fees – applications made by small companies**

**15A.**—(1) Schedule 2A to these Regulations shall have effect with respect to the fee payable in connection with an application made by or on behalf of a small company.

(2) For the purpose of these Regulations, a company is a small company if, for the financial year before that in which the application is made the amount of its turnover for the year is not more than 50% of the amount for the time being specified in section 248(1)(a) of the Companies Act 1985(a); and

(a) its balance sheet total (as defined in section 248(3) of that Act) is not more than the amount for the time being specified in section 248(1)(b) of that Act; or

(b) the average number of persons employed by the company in the financial year before that in which the application is made (determined on a weekly basis) does not exceed the amount for the time being specified in section 248(1)(c) of that Act.".

**Revocation of regulation 20(4) of the principal Regulations**

**15.** Regulation 20(4) of the principal Regulations (transitional provision) is hereby revoked.

**Amendment of Part I of Schedule 1 to the principal Regulations**

**16.** In paragraph 1 of Part I of Schedule 1 to the principal Regulations (interpretation)–

(a) in the definition of "complex application"

(i) for sub-paragraph (g) there shall be substituted the following–

"(g) relates to a medicinal product which is a controlled release preparation except where the application is for a variation in connection with such preparation and does not relate to a matter mentioned in sub-paragraph (b), (c), (d), (f), (j), (k) or (n) of this definition.";

(ii) at the end of sub-paragraph (j) there shall be deleted the word "or";

(iii) after sub-paragraph (k) there shall be inserted the following sub-paragraphs–

"(l) relates to a medicinal product which is an influenza vaccine and in respect of which the manufacturer or the manufacturing process is different from that specified in any other product licence which the applicant holds in respect of that product;

(m) is for a product licence for a medicinal product which is an influenza vaccine, except where it relates only to an influenza vaccine containing a different strain or strains from that specified in any other product licence which the applicant holds; or

---

(a) 1985 c.6, as modified by the Companies (Modified Accounts) Amendment Regulations 1986 (S.I. 1986/1865). The figures currently specified in section 248(1)(a), (b) and (c) are, respectively, £2 million, £975,000 and 50.

**Amendment of regulation 7 of the principal Regulations**

**8.** In regulation 7 of the principal Regulations (variations of clinical trial certificates) for "£175" there shall be substituted "£300".

**Amendment of regulation 8 of the principal Regulations**

**9.** In regulation 8 of the prinicipal Regulations (change of name or address in clinical trial certificates) for "£50" there shall be substituted "£85".

**Amendment of regulation 9 of the principal Regulations**

**10.** For regulation 9 of the principal Regulations (applications for multiple variations) there shall be substituted the following–

**"Applications for multiple variations**

**9.**—(1) Subject to paragraphs (2) and (3) of this regulation, a separate fee shall be payable in respect of each variation of each provision of a licence or certificate applied for in any one application.

(2) In respect of a variation which does not require a full assessment of the application separate from that required in respect of another variation applied for in the same application, the fee payable shall be 50% of that payable in accordance with regulation 6 or regulation 7.

(3) In respect of a variation which is wholly consequential upon another variation of a provision of a licence or certificate which is applied for in the same application, no separate fee shall be payable.

**Amendment of regulation 10 of, and additional regulation 10A to, the principal Regulations**

**11.**—(1) In regulation 10 of the principal Regulations (renewal of licences) for "Subject to regulations 12, 16 and 20" there shall be substituted "Subject to regulations 10A, 12, 16 and 20".

(2) After regulation 10 of the principal Regulations there shall be inserted the following regulation–

**"Inspections in connection with multiple applications for renewal of licences**

**10A.** Where an inspection mentioned at regulation 10(b) of these Regulations is made at a site which has been named as a possible site for manufacture of a medicinal product by more than one applicant for a renewal of–

(a) a product licence and that site is located outside the United Kingdom; or

(b) a manufacturer's licence and that site is located in the United Kingdom,

the fee in respect of that inspection shall be payable in equal proportions by each applicant for such renewal.".

**Amendment of regulation 11 of the principal Regulations**

**12.** In regulation 11 of the principal Regulations (renewal of certificates) for "£2,000" there shall be substituted "£3,400".

**Amendment of regulation 13 of the principal Regulations**

**13.** After paragraph (3) of regulation 13 to the principal Regulations (fees for inspections of sites located outside the United Kingdom) there shall be inserted the following–

" (3A) Where a fee is payable under paragraph (1) above in respect of an inspection of a site located in the United Kingdom, the fee shall be payable in equal proportions by each holder of a manufacturer's licence in which that site is named as a possible site for manufacture of the medicinal product in respect of which the manufacturer's licence is granted.".

**"Fees payable in connection with applications**

**2A.**—(1) Subject to paragraphs (2) and (3) of this regulation, the amount of a fee payable in connection with an application is that payable in accordance with these Regulations as in force when the application is made.

(2) The amount of a fee payable in connection with an application for the renewal of a licence or certificate made more than four months before the date on which it is due to expire is that payable in accordance with these Regulations as in force on that date.

(3) The amount of a fee payable in respect of an inspection is that payable in accordance with these Regulations as in force when the inspection is made.".

**Amendment of regulation 3 of, and additional regulation 3A to, the principal Regulations**

**4.**—(1) In regulation 3 of the principal Regulations (applications for licences) for the words "Subject to regulations 16 and 20", there shall be substituted "Subject to regulations 3A, 16 and 20".

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

**"Inspections in connection with multiple applications for licences**

**3A.** Where an inspection mentioned at regulation 3(b) of these Regulations is made at a site which has been named as a possible site for manufacture of a medicinal product by more than one applicant for–

(a) a product licence and that site is located outside the United Kingdom; or

(b) a manufacturer's licence and that site is located in the United Kingdom,

the fee in respect of that inspection shall be payable in equal proportions by each applicant for such licence.".

**Amendment of regulation 4 of the principal Regulations**

**5.** In regulation 4 of the principal Regulations (applications for clinical trial certificates) for "£8,000" there shall be substituted "£13,600".

**Amendment of regulation 5 of the principal Regulations**

**6.** Regulation 5 of the principal Regulations (applications for certificates for exports of medicinal products) shall be amended as follows–

(a) in paragraph (1)(a) for "£100" there shall be substituted "£170";

(b) in paragraph (1)(b) for "£50" there shall be substituted "£85";

(c) in paragraph (1)(c)–

(i) in head (i) for "£10" there shall be substituted "£15";

and

(ii) in head (ii) for "£50" there shall be substituted "£85".

**Amendment of regulation 6 of, and additional regulation 6A to, the principal Regualtions**

**7.**—(1) In regulation 6 of the principal Regulations (variations of licences) for "Subject to regulations 9, 16 and 20" there shall be substituted "Subject to regulations 6A, 9, 16 and 20".

(2) After regulation 6 to the principal Regulations there shall be inserted the following regulation–

**"Inspections in connection with multiple applications for variations of licences**

**6A.** Where an inspection mentioned at regulation 6(b) of these Regulations is made at a site which has been named as a possible site for manufacture of a medicinal product by more than one applicant for a variation to–

(a) a product licence and that site is located outside the United Kingdom; or

(b) a manufacturer's licence and that site is located in the United Kingdom,

the fee in respect of that inspection shall be payable in equal proportions by each applicant for such variation.".

STATUTORY INSTRUMENTS

# 1990 No. 210

# MEDICINES

# The Medicines (Fees Relating to Medicinal Products for Human Use) Amendment Regulations 1990

| | |
|---|---|
| *Made - - - -* | *8th February 1990* |
| *Laid before Parliament* | *13th February 1990* |
| *Coming into force* | *5th March 1990* |

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 the powers conferred by section 1(1) of the Medicines Act 1971, (a) and now vested in them (b) 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 (c), hereby make the following Regulations:–

**Citation, interpretation and commencement**

**1.** These Regulations which may be cited as the Medicines (Fees Relating to Medicinal Products for Human Use) Amendment Regulations 1990, amend the Medicines (Fees Relating to Medicinal Products for Human Use) Regulations 1989 (d) (hereinafter referred to as "the principal Regulations") and shall come into force on 5th March 1990.

**Amendment of regulation 1(4) of the principal Regulations**

**2.** In regulation 1(4) of the principal Regulations (applications made at the specific invitation of the licensing authority), before the words "No fee shall be payable under these Regulations" there shall be inserted "Subject to paragraph 1A of Part II of Schedule 1 to these Regulations.".

**Additional regulation 2A to the principal Regulations**

**3.** In Part 1 of the principal Regulations after regulation 2 (interpretation), there shall be inserted the following regulation–

(a) 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.

(b) 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).

(c) *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.

(d) S.I. 1989/418.