STATUTORY INSTRUMENTS

2002 No. 542

MEDICINES

FEES AND CHARGES

The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 2002

Made - - - -	*11th March 2002*
Laid before Parliament	*11th March 2002*
Coming into force	*1st April 2002*

The Secretary of State, being a Minister designated for the purposes of section 2(2) of the European Communities Act 1972**(a)** in relation to medicinal products**(b)**, in exercise of the powers conferred upon him by the said section 2(2), the Secretary of State, with the consent of the Treasury, in exercise of the powers conferred upon him by section 56(1) and (2) of the Finance Act 1973**(c)**, the Secretary of State concerned with health in England, the Minister of Agriculture, Fisheries and Food, the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, acting jointly and with the consent of the Treasury, in exercise of powers conferred upon them by section 1(1) and (2) of the Medicines Act 1971**(d)**, or, as the case may be, powers conferred by those provisions and now vested in them**(e)**, and in each case in exercise of all other powers respectively enabling them in that behalf, after consultation in accordance with section 129(6) of the Medicines Act 1968**(f)**, as extended by section 1(3)(b) of the Medicines Act 1971, with such organisations as appear to them to be representative of interests likely to be substantially affected, hereby make the following Regulations:—

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 2002 and shall come into force on 1st April 2002.

(2) In these Regulations—

(a) 1972 c.68.
(b) S.I. 1972/1811.
(c) 1973 c.51.
(d) 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 used in that section have the same meaning as in the Medicines Act 1968 (c.67), as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388 and by article 5 of, and the Schedule to, S.I. 1999/3142; *see* therefore section 1(1) of the 1968 Act, which contains a definition of "the Ministers' " which is relevant to the powers being exercised in the making of these Regulations. *See also* regulation 9(12) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144), by virtue of which the references in section 1(1) and (2)(b) of the 1971 Act to a licence under Part II of the 1968 Act include reference to a marketing authorization under the 1994 Regulations.
(e) In the case of the Secretary of State concerned with health in England, by virtue of articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142; in the case of the Minister of Agriculture, Fisheries and Food, by virtue of articles 2(2) and 5 of, and the Schedule to, S.I. 1999/3142; in the case of the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47).
(f) 1968 c.67.

"the Devices Regulations" means the Medical Devices (Consultation Requirements) (Fees) Regulations 1995**(a)**;

"the General Fees Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995**(b)**;

"the Homoeopathic Products Regulations" means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994**(c)**; and

"the Marketing Authorisations Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994**(d)**.

Amendment of the Homoeopathic Products Regulations

2.—(1) In regulation 6 of the Homoeopathic Products Regulations (grant of a certificate), omit paragraph (b).

(2) In regulation 9 of the Homoeopathic Products Regulations**(e)** (suspension and revocation), omit paragraph (3).

(3) In regulation 14 of the Homoeopathic Products Regulations**(f)** (fees for variations of certificates)—

(a) in paragraph (1)(a), for "£95" substitute "£103";

(b) in paragraph (1)(b)(i), for "£95" substitute "£103";

(c) in paragraph (1)(b)(ii), for "£45" substitute "£51.50";

(d) in paragraph (2)(a), for "£185" substitute "£200";

(e) in paragraph (2)(b)(i), for "£185" substitute "£200";

(f) in paragraph (2)(b)(ii), for "£185" substitute "£200";

(g) in paragraph (2)(b)(iii), for "£88" substitute "£100"; and

(h) in paragraph (2)(b)(iv), for "£44" substitute "£50".

(4) In regulation 15(1) of the Homoeopathic Products Regulations**(g)** (fees payable by holders of certificates), for "£12" substitute "£13".

(5) In the Table in Schedule 2 to the Homoeopathic Products Regulations**(h)** (fees for applications for the grant of certificates of registration)—

(a) in column (2) (fees for applications in respect of products prepared from not more than 5 homoeopathic stocks)—

(i) for "£113" substitute "£122",

(ii) for "£341" substitute "£368", and

(iii) for "£562" substitute "£607"; and

(b) in column (3) (fees for other applications)—

(i) for "£280" substitute "£302",

(ii) for "£502" substitute "£542", and

(iii) for "£736" substitute "£795".

Amendment of the Marketing Authorisations Regulations

3.—(1) The Marketing Authorisations Regulations are amended as follows.

(2) In regulation 5 (consideration, and grant or refusal, of an application for, or for renewal or variation of, a United Kingdom marketing authorization), omit paragraph (2).

(3) After regulation 5 (consideration, and grant or refusal, of an application for, or for renewal or variation of, a United Kingdom marketing authorization) insert the following regulation—

(a) S.I. 1995/449; amended by S.I.1998/574, 1999/566, 2000/592 and 2001/795.
(b) S.I. 1995/1116; amended by S.I. 1996/683, 1998/574, 1999/566, 2000/592 and 3031, and 2001/795.
(c) S.I. 1994/105; amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2000/592 and 2001/795.
(d) S.I. 1994/3144; amended by S.I. 1998/3105, 2000/292, 2001/795 and 2002/236.
(e) As amended by regulation 3 of S.I. 1994/899.
(f) As amended by regulation 3(2) of S.I. 2001/795.
(g) As amended by regulation 3(3) of S.I. 2001/795.
(h) As amended by regulation 3(4) of S.I. 2001/795.

"**Classification of medicinal products**

5A.—(1) Each marketing authorization granted by the licensing authority on or after 1st April 2002 shall be granted subject to a condition that the medicinal product to which the authorization relates is to be available—

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale.

(2) Where prior to 1st April 2002 a medicinal product is subject to a marketing authorization and that authorization contains a statement that it is to be available on one or more of the following bases—

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale,

it is a condition of the marketing authorization from 1st April 2002 that the product is to be available only on that basis or, as the case may be, those bases.".

(4) In regulation 6 (revocation, suspension or variation of a United Kingdom marketing authorization or the suspension of the use or marketing of medicinal products), omit paragraph (8).

(5) Regulation 8 (control of sale or supply of relevant medicinal products) is hereby revoked.

(6) In paragraph 6(2) of Schedule 5 (labels), for head (a) substitute—

"(a) if the product would be subject to restrictions imposed under section 58 of the Act if it contained a higher proportion or level of any substance, except where the product is for external use only or contains any of the substances described in head (c) of this sub-paragraph, the words "Warning. Do not exceed the stated dose";".

Amendment of regulation 3 of the Devices Regulations

4. In regulation 3 of the Devices Regulations**(a)** (fees)—

(a) in paragraph (1)(a), for "£3,029" substitute "£3,271";

(b) in paragraph (1)(b), for "£6,726" substitute "£7,264";

(c) in paragraph (2)(a), for "£599" substitute "£647";

(d) in paragraph (2)(b), for "£1,676" substitute "£1,810";

(e) in paragraph (3)(a), for "£2,285" substitute "£3,271";

(f) in paragraph (3)(b), for "£6,406" substitute "£7,264";

(g) in paragraph (4)(a), for "£570" substitute "£647";

(h) in paragraph (4)(b), for "£1,596" substitute "£1,810";

(i) in paragraph (5)(a), for "£30,972" substitute "£33,450"; and

(j) in paragraph (5)(b), for "£7,690" substitute "£8,305".

Amendment of the General Fees Regulations

5.—(1) The General Fees Regulations are amended as follows.

(2) In regulation 2(1) (interpretation) after the definition of "the 2001 Directive"**(b)** insert the following definition—

(a) As amended by regulation 4 of S.I. 2001/795.
(b) The definition of "the 2001 Directive" was inserted by regulation 16(a) of S.I. 2002/236.

""Directive 75/319/EEC" means Council Directive 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products**(a)**, as amended**(b)**;".

(3) After Part IV of the General Fees Regulations (capital fees for applications for renewals of clinical trial certificates and for certain manufacturer's licences and for associated inspections) insert the following Part—

"PART IVA

CAPITAL FEES FOR REGULATORY ASSISTANCE GIVEN BY THE UNITED KINGDOM ACTING AS REFERENCE MEMBER STATE RELATING TO THE ASSESSMENT OF APPLICATIONS FOR THE RENEWAL OF SPECIFIED MARKETING AUTHORIZATIONS

12A.—(1) Subject to regulation 19, where—

(a) an application is made to the licensing authority for the renewal of a United Kingdom marketing authorization in relation to a medicinal product which has been subject to the procedures specified in paragraph (2); and

(b) the United Kingdom is to provide regulatory assistance acting as reference Member State in relation to that application,

there shall be payable by the applicant the fee prescribed in Part IV of Schedule 1 in connection with that regulatory assistance.

(2) The procedures referred to in paragraph (1) are—

(a) the procedures laid down in Articles 7 and 7a of Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products**(c)**, as amended**(d)**, and in Articles 17 and 18 of the 2001 Directive**(e)**;

(b) the procedures laid down in Article 9(4) of Directive 75/319/EEC and in Article 28(4) of the 2001 Directive;

(c) the procedures laid down in Articles 10 to 14 of Directive 75/319/EEC and in Articles 29 to 34 of the 2001 Directive;

(d) referral to the Committee for Proprietary Medicinal Products**(f)** in accordance with Council Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology**(g)**, if the opinion of the Committee in accordance with Article 4.1 of that Directive was given before 1st January 1995.

(3) For the purposes of this regulation and Part IV of Schedule 1, the United Kingdom provides regulatory assistance acting as reference Member State in relation to an application for renewal of a United Kingdom marketing authorization where the licensing authority prepares or updates an assessment report in respect of the medicinal product in question for the purpose of making such report available to the competent authorities of another EEA state in which an application has been made for the renewal of a marketing authorization relating to that product in that state.

(a) OJ No. L 147, 9.6.1975, p.13.

(b) This Directive has been amended by Council Directive 78/420/EEC (OJ No. L 123, 11.5.1978, p.26), Council Directive 83/570/EEC (OJ No. L 332, 28.11.1983, p.1), Council Directive 89/341/EEC (OJ No. L 142, 25.5.1989, p.11), Council Directive 89/342/EEC (OJ No. L 142, 25.5.1989, p.14), Council Directive 89/343/EEC (OJ No. L 142, 25.5.1989, p.16), Council Directive 89/381/EEC (OJ No. L 181, 28.6.1989, p.44), Council Directive 92/27/EEC (OJ No. L 113, 30.4.1992, p.8), Council Directive 92/73/EEC (OJ No. L 297, 13.10.1992, p.8), Council Directive 93/39/EEC (OJ No. L 214, 24.8.1993, p.22), and Commission Directive 2000/38/EC (OJ No. L 139, 10.6.2000, p.28).

(c) OJ No. L 22, 9.2.65, p.369.

(d) This Directive has been amended by Council Directive 75/319/EEC (OJ No. L 147, 9.6.1975, p.13), Council Directive 83/570/EEC (OJ No. L 332, 28.11.1983, p.1), Council Directive 87/21/EEC (OJ No. L 15, 17.1.1987, p.36), Council Directive 89/341/EEC (OJ No. L 142, 25.5.1989, p.11), Council Directive 89/342/EEC (OJ No. L 142, 25.5.1989, p.14), Council Directive 89/343/EEC (OJ No. L 142, 25.5.1989, p.16), Council Directive 89/381/EEC (OJ No. L 181, 28.6.1989, p.44) and Council Directive 93/39/EEC (OJ No. L 214, 24.8.1993, p.22).

(e) *See* Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ No. L 311, 28.11.2001, p.67).

(f) *See* Article 27 of Directive 2001/83/EC.

(g) OJ No. L 15, 17.1.1987, p.38.

12B. Subject to regulation 19, all sums payable by way of fees under regulation 12A(1) shall be payable at the time when the application for renewal of the United Kingdom marketing authorization is made to the licensing authority.".

(4) In Part I of Schedule 1 (interpretation), in paragraph 1, in the definition of "complex application", at the end of sub-paragraph (i) add ", except where a European Pharmacopoeia certificate of suitability covering the active ingredient has been submitted with the application".

(5) In Part II of Schedule 1 (capital fees for applications for authorizations, licences and certificates)—

(a) in paragraph 1—

(i) in sub-paragraph (1), for "paragraphs 2, 3 and 4" substitute "paragraphs 1A, 2, 3 and 4", and

(ii) in sub-paragraph (2), for "paragraphs 3 and 4" substitute "paragraphs 1A, 3 and 4";

(b) after paragraph 1 insert the following paragraph—

"**1A.**—(1) Subject to paragraph 4, where an application, other than a major application, includes a reclassification element, an amount of £6,000 shall be payable in addition to the amount payable under paragraph 1 in respect of that application.

(2) For the purposes of this paragraph and paragraph 4, an application includes a reclassification element if—

(a) the medicinal product in question is to be available in the United Kingdom only from a pharmacy, unless there is an analogous medicinal product available in the United Kingdom only from a pharmacy or on general sale; or

(b) the medicinal product in question is to be available in the United Kingdom on general sale, unless there is an analogous medicinal product also so available.

(3) For the purposes of this paragraph, an analogous medicinal product is a medicinal product which has a United Kingdom marketing authorization or a Community marketing authorization and which—

(a) has the same active ingredient, route of administration and use;

(b) has the same strength or a higher strength;

(c) has the same dosage or daily dosage, or a higher dosage or daily dosage; and

(d) is for sale or supply at the same quantity or a greater quantity,

as the medicinal product in relation to which the application is made."; and

(c) in paragraph 4—

(i) in sub-paragraph (1), for "sub-paragraphs (2) and (3)" substitute "sub-paragraphs (2) to (4)"; and

(ii) after sub-paragraph (3), insert the following sub-paragraph—

"(4) If the application includes any applications for marketing authorizations that include a reclassification element, the amount payable shall be the amount payable in accordance with sub-paragraphs (1) to (3) plus—

(a) in respect of the first marketing authorization applied for that includes a reclassification element, the additional amount payable under paragraph 1A(1); and

(b) in respect of each other marketing authorization applied for that includes a reclassification element, £458.".

(6) In Part III of Schedule 1 (capital fees for applications for variations of marketing authorizations, licences and certificates)—

(a) in paragraph 1—

(i) before the definition of "Type I Application" insert the following definition—

" "reclassification variation application" means an application for variation of a marketing authorization which has the effect that a medicinal product to which that authorization relates—

(a) is to be available only from a pharmacy, where previously it was available only on prescription;

(b) is to be available on general sale, where previously it was available only on prescription or only from a pharmacy;"; and

(ii) in the definition of "Type II Application", for the words from "neither a Type I Application" to the end substitute "not a reclassification variation application, a Type I Application, a Type II Complex Variation Application or a change to which Annex II to Commission Regulation (EC) 541/95 applies";

(b) in paragraph 2—

(i) for "13 and 14" substitute "13 to 15"; and

(ii) after sub-paragraph (c) insert the following sub-paragraph—

"(d) where the application is a reclassification variation application, £6,000.";

(c) after paragraph 5, insert the following paragraph—

"**5A.**—(1) Where an application is a reclassification variation application to which this paragraph applies, the fee payable under regulation 7(1) in connection with the application for variation of a marketing authorization shall be £458.

(2) This paragraph applies to a reclassification variation application which would have the effect that a medicinal product to which the marketing authorization relates—

(a) is to be available only from a pharmacy (where previously it was available only on prescription), if an analogous medicinal product is available only from a pharmacy or on general sale; or

(b) is to be available on general sale (where previously it was available only on prescription or only from a pharmacy), if an analogous medicinal product is available on general sale.

(3) For the purposes of this paragraph, an analogous medicinal product is a medicinal product which has a United Kingdom marketing authorization or a Community marketing authorization and which—

(a) has the same active ingredient, route of administration and use;

(b) has the same strength or a higher strength;

(c) has the same dosage or daily dosage, or a higher dosage or daily dosage; and

(d) is for sale or supply at the same quantity or a greater quantity,

as the medicinal product in relation to which the variation application is made. ";

(d) in paragraph 6—

(i) after sub-paragraph (a)(vii)**(a)** insert the following sub-paragraph—

"(viii) if the marketing authorization was not a parallel import licence, the application for that variation would be a reclassification variation application to which paragraph 5A of this Schedule applies,";

(ii) for sub-paragraph (b) substitute the following sub-paragraphs—

"(b) where the application would be a reclassification variation application to which paragraph 5A of this Schedule does not apply, if the marketing authorization was not a parallel import licence, shall be £6,000; and

(c) in any other case, shall be £270.";

(e) in paragraph 12, for "paragraph 14" substitute "paragraphs 14 and 15"; and

(f) after paragraph 14, insert the following paragraph—

"**Multiple reclassification variation applications**

15. Where more than one reclassification variation application is made at the same time by the same applicant, each relating to medicinal products which have the same active ingredient or combination of ingredients, the fee payable under regulation 7(1)—

(a) Paragraph 6(a)(vii) of Part III of Schedule 1 was inserted by regulation 4 of S.I. 1999/566.

(a) if one or more of the applications is an application to which paragraph 5A does not apply—

(i) in connection with the first application to which paragraph 5A does not apply, shall be the appropriate amount specified in this Part of the Schedule;

(ii) in connection with each other application to which paragraph 5A does not apply, shall be £458; and

(iii) in connection with each other application to which paragraph 5A does apply, shall be £229;

(b) in any other case—

(i) in connection with the first application, shall be the appropriate amount specified in this Part of the Schedule; and

(ii) in connection with each other application, shall be £229.".

(7) After Part III of Schedule 1 (capital fees for applications for variations of authorizations, licences and certificates) insert the following Part—

"PART IV

CAPITAL FEES FOR REGULATORY ASSISTANCE GIVEN BY THE UNITED KINGDOM ACTING AS REFERENCE MEMBER STATE RELATING TO THE ASSESSMENT OF APPLICATIONS FOR THE RENEWAL OF SPECIFIED MARKETING AUTHORIZATIONS

1. Subject to paragraph 2, the fee payable under regulation 12A(1) in connection with regulatory assistance provided by the United Kingdom acting as reference Member State where an application is made to the licensing authority for the renewal of a United Kingdom marketing authorization in relation to a medicinal product which has been subject to the procedures specified in regulation 12A(2), shall be—

(a) if the application for renewal relates to a medicinal product which, at the time the United Kingdom marketing authorization was granted, contained a new active ingredient and that renewal is the first renewal in relation to which the United Kingdom is to provide regulatory assistance acting as reference Member State, a fee of £6,784,

(b) in every other case, a fee of £554.

2. Where more than one application falling within regulation 12A(1) is made by the same applicant at the same time, each relating to medicinal products which have the same active ingredient or combination of ingredients, dosage form, therapeutic indications and Periodic Safety Update Reports, and the United Kingdom marketing authorizations for those products have the same date for renewal, the fee payable under regulation 12A(1) shall be—

(a) if the applications fall within paragraph 1(a)—

(i) in connection with the first application considered by the licensing authority, the amount specified in paragraph 1(a), and

(ii) in connection with each other application, a fee of £554;

(b) if the applications fall within paragraph 1(b)—

(i) in connection with the first application considered by the licensing authority, the amount specified in paragraph 1(b), and

(ii) in connection with each other application, a fee of £277.".

(8) In Schedule 5 (waiver, reduction or refund of capital fees), after paragraph 2A**(a)**, insert the following paragraph—

"**2B.**—(1) Where—

(a) Paragraph 2A was inserted by regulation 5(12) of S.I. 2001/795.

(a) an application for a marketing authorization includes a reclassification element in accordance with paragraph 1A of Part II of Schedule 1; and

(b) the licensing authority is satisfied that the reclassification element does not require consideration by a committee established under section 4 (establishment of committees) of the Act or by the Medicines Commission,

50% of the additional amount payable under paragraphs 1A(1) or 4(4)(a) of Part II of that Schedule shall be refunded, or if it has not yet been paid, shall be waived.

(2) Where—

(a) an application for variation of a marketing authorization is a reclassification variation application (not being an application falling within paragraph 5A of Part III of Schedule 1); and

(b) the licensing authority is satisfied that the application does not require consideration by a committee established under section 4 (establishment of committees) of the Act or by the Medicines Commission,

50% of the fee payable under paragraphs 2(2)(d) or 15(a)(i) of Part III of Schedule 1 shall be refunded, or if it has not yet been paid, shall be waived.

(3) Where—

(a) an application for variation of a parallel import licence falls within paragraph 6(b) of Part III of Schedule 1; and

(b) the licensing authority is satisfied that the application does not require consideration by a committee established under section 4 (establishment of committees) of the Act or by the Medicines Commission,

50% of the fee payable under that paragraph shall be refunded, or if it has not yet been paid, shall be waived.

(4) For the purposes of paragraphs (1) to (3), a reclassification element or, as the case may be, a variation application does not require consideration by a committee established under section 4 (establishment of committees) of the Act or by the Medicines Commission where—

(a) the licensing authority was satisfied that the application did not require consideration by such a committee or that Commission; and

(b) the committee or the Commission are consulted only by virtue of, or in accordance with, paragraph 5 of Schedule 2 to the 1994 Regulations (procedural provisions relating to the grant, renewal, variation, revocation and suspension of United Kingdom marketing authorizations).".

(9) In each provision of the General Fees Regulations specified in the entries in column (1) of the Schedule to these Regulations (the content of which is described in column (2) of that Schedule), for the amount specified opposite that provision in column (3) of that Schedule substitute the amount specified opposite that provision in column (4) of that Schedule.

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
Department of Health

6th March 2002

Whitty
Parliamentary Under Secretary of State,
11th March 2002 Department for Environment, Food and Rural Affairs

Bairbre de Brún
11th March 2002 Minister of Health, Social Services and Public Safety

Bríd Rodgers
11th March 2002 Minister of Agriculture and Rural Development

We consent,

Anne McGuire
Nick Ainger
6th March 2002 Two of the Lords Commissioners of Her Majesty's Treasury

SCHEDULE

Regulation 5(9)

Column (1) Provision in the General Regulations	Column (2) Subject matter	Column (3) Old amount	Column (4) New amount
Regulation 6	Applications for certificates by exports of medicinal products		
Paragraph (1)(a)		£100	£108
Paragraph (1)(b)		£44	£48
Paragraph (1)(c)(i)		£44	£48
Paragraph (1)(c)(ii)		£22	£24
Regulation 10	Renewal of clinical trial certificates	£1,885	£2,036
Regulation 11(1)	Renewals of certain manufacturer's licences	£107	£116
Part II of Schedule I	Capital fees for applications for authorizations, licences and certificates		
In column 2 of the Table in paragraph 1(1)			
Entry 1(a)		£22,622	£24,431
Entry 1(b)		£48,389	£52,260
Entry 1(c)		£69,127	£74,657
Entry 2(a)		£13,196	£14,252
Entry 2(b)		£18,853	£20,361
Entry 3(a)		£4,835	£5,222
Entry 3(b)		£6,913	£7,466
Entry 4		£1,885	£2,036
Entry 5		£1,256	£1,356
Entry 6		£310	£335
Paragraph 5(1)(a)		£120	£130
Paragraph 5(1)(b)		£227	£245
Paragraph 5(1)(c)		£2,070	£2,236
Paragraph 6(1)		£814	£879
Paragraph 6(2)		£598	£646
Paragraph 6(4)		£262	£283
Paragraph 7		£14,579	£15,940
Part IIA of Schedule 1**(a)**	Capital fees for assistance in obtaining marketing authorizations in other EEA states		
Paragraph 2(a)(i)		£30,000	£32,400
Paragraph 2(a)(ii)		£20,000	£21,600
Paragraph 2(b)(i)		£7,500	£8,100
Paragraph 2(b)(ii)		£5,000	£5,400
Paragraph 2(c)(i)		£3,000	£3,240
Paragraph 2(c)(ii)		£2,500	£2,700
Paragraph 2(d)		£1,795	£1,939
Part III of Schedule 1	Capital fees for applications for variations of authorizations, licences and certificates		
Paragraph 2(a)		£184	£198
Paragraph 2(b)		£424	£458
Paragraph 2(c)		£6,282	£6,784
Paragraph 3(a)		£288	£310
Paragraph 3(b)		£514	£554
Paragraph 3(c)		£9,802	£10,586
Paragraph 6(a)		£120	£130
Paragraph 7(a)		£113	£122
Paragraph 7(b)		£227	£245

(a) Part IIA was inserted by regulation 6 of S.I. 2000/3031.

Column (1) Provision in the General Regulations	Column (2) Subject matter	Column (3) Old amount	Column (4) New amount
Paragraph 8		£113	£122
Paragraph 9		£262	£282
Paragraph 10		£113	£122
Paragraph 11		£185	£200
Paragraph 12		£95	£103
Schedule 2	Fees for inspections		
Paragraph 2(a)(i)		£1,964	£2,121
Paragraph 2(a)(ii)		£3,643	£3,934
Paragraph 2(a)(iii)		£4,400	£4,752
Paragraph 2(a)(iv)		£7,541	£8,144
Paragraph 2(b)(i)		£2,136	£2,307
Paragraph 2(b)(ii)		£4,400	£4,752
Paragraph 2(b)(iii)		£6,911	£7,464
Paragraph 2(b)(iv)		£12,568	£13,573
Paragraph 2(c)(i)		£754	£814
Paragraph 2(c)(ii)		£2,110	£2,278
Paragraph 2(c)(iii)		£3,153	£3,405
Paragraph 2(c)(iv)		£5,906	£6,378
Paragraph 2(d)		£143	£154
Paragraph 5(1)		£395	£427
Paragraph 5(1)		£867	£936
Part III of Schedule 3	Periodic fees for marketing authorizations and licences		
In column 2 of the Table in paragraph 1			
Entry 1		£12,209	£13,186
Entry 2(a)		£5,027	£5,429
Entry 2(b)(i)		£1,257	£1,358
Entry 2(b)(ii)		£628	£678
Entry 2(b)(iii)		£204	£220
Entry 2(c)(i)		£550	£594
Entry 2(c)(ii)		£275	£297
Entry 2(c)(iii)		£102	£110
Entry 2(d)(i)		£227	£245
Entry 2(d)(ii)		£113	£122
Entry 2(d)(iii)		£50	£54
Entry 2(e)		£62	£67
Paragraph 2(a)		£280	£302
Paragraph 2(b)		£138	£149
Paragraph 2(c)		£58	£63
Paragraph 3(a)		£5,027	£5,429
Paragraph 3(b)		£3,394	£3,666
Paragraph 7		£251	£271
Paragraph 8(1)		£155	£167
Paragraph 8(2)		£93	£100

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make further amendments to the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 ("the Homoeopathic Products Regulations"), the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 ("the Marketing Authorisations Regulations"), the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 ("the Devices Regulations") and the Medicines (Products for Human Use-Fees) Regulations 1995 ("the General Fees Regulations").

The Homoeopathic Products Regulations implemented in part Council Directive 92/73/EEC**(a)** (now repealed and re-enacted in Directive 2001/83/EC**(b)**) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for human use. Regulation 2 of these Regulations amend the Homoeopathic Products Regulations. Regulation 2(1) and (2) amends regulations 6 and 9 of those Regulations to remove the requirement that decisions to grant, suspend and revoke a certificate of registration must be published in the Gazette. Regulation 2(3) increases the amounts of the fees payable for variations of certificates of registration, regulation 2(4) increases the fee payable by holders of certificates of registration and regulation 2(5) increases the amounts of the capital fees payable for applications for certificates of registration. These increases average overall 9.5%.

The Marketing Authorisations Regulations implemented in part the following provisions of European Community law: Council Directives 65/65/EEC**(c)**, 75/318/EEC**(d)**, 75/319/EEC**(e)** and the Regulations adopted by the Commission under Article 15 of that Directive, 89/342/EEC**(f)**, 89/343/EEC**(g)**, 89/381/EEC**(h)**, 92/26/EEC**(i)**, 92/27/EEC**(j)** and 92/73/EEC **(k)**, now repealed and re-enacted by Directive 2001/83/EC**(l)**, and Council Regulation (EEC) No. 2309/93**(m)** and the Regulations adopted by the Commission under Articles 15.4 or 22.1 of that Regulation. They provide for the manner of making applications for the grant, renewal or variation of a United Kingdom marketing authorization and for procedures for consideration, revocation, suspension and related matters. Regulation 3 of these Regulations amends the Marketing Authorisations Regulations. Regulation 3(2) and (4) amends regulations 5 and 6 of those Regulations so as to remove the requirement that decisions to grant, revoke, suspend or vary a marketing authorization must be published in the Gazette. Regulation 3(3) inserts new regulation 5A into those Regulations (which relates to the provisions of Directive 92/26/EC, re-enacted as Title VI in Directive 2001/83/EC), so as to provide that the classification of a medicinal product is a condition of the marketing authorization relating to that product, and regulation 3(5) and (6) makes consequential amendments.

The Devices Regulations prescribe the fees which are payable where a notified body consults the competent body in accordance with Council Directive 93/42/EEC**(n)** concerning medical devices. Regulation 4 of these Regulations amends the Devices Regulations by increasing the amounts of the fees specified in regulation 3 of those Regulations by an average overall of 12.5%.

The General Fees Regulations make provision for the fees payable under the Medicines Act 1971 relating to marketing authorizations, licences and certificates in respect of medicinal products for human use. Regulation 5 of these Regulations amend those Regulations as follows. Regulation 5(3) and (7) inserts new Part IVA into the General Fees Regulations, and a new Part IV into Schedule 1 to those Regulations. These contain provisions relating to the setting of new capital fees in cases where the United Kingdom provides assistance to another EEA state arising out of an application for the renewal of a United Kingdom marketing authorization relating to a medicinal product that has been subject to certain procedures for the mutual recognition and harmonisation of marketing authorizations within the Community. Regulation 5(2) makes an

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(a) OJ No. L 297, 13.10.1992, p.8.
(b) *See* articles 1(5), 13 to 16, 53, 68, 69, 85, 100, 119 and 124.
(c) OJ No. L 22, 9.2.1965, p.369.
(d) OJ No. L 147, 9.6.1975, p.1.
(e) OJ No. L 147, 9.6.1975, p.13.
(f) OJ No. L 142, 25.5.1989, p.14.
(g) OJ No. L 142, 25.5.1989, p.16.
(h) OJ No. L 181, 28.6.1989, p.44.
(i) OJ No. L 113, 30.4.1992, p.5.
(j) OJ No. L 113, 30.4.1992, p.8.
(k) OJ No. L 297, 13.10.1992, p.8.
(l) OJ No. L 311, 28.11.2001, p.67.
(m) OJ No. L 214, 24.8.1993, p.1.
(n) OJ No. L 169, 12.7.1993, p.1; amended by Directive 98/79/EC (OJ No. L 331, 7.12.1998, p.1).

amendment consequential on these provisions. Regulation 5(4) amends Part I of Schedule 1 to those Regulations so as to provide that where an application for the grant of a marketing authorization names a manufacturer of the active ingredient of the medicinal product in question different from the manufacturer of that ingredient in a product in respect of which a marketing authorization has previously been granted, the application is not a complex application if a European Pharmacopoeia certificate of suitability covering the active ingredient has been submitted with the application. Regulation 5(5) and (6) amends Parts II and III of Schedule 1 to those Regulations so as to provide that an additional fee is payable where an application for the grant of a marketing authorization, or for the variation of a marketing authorization, changes whether a medicinal product is available only on prescription, only from a pharmacy or on general sale, or provides that the basis on which it is to be made available is different from that of certain similar products. Regulation 5(8) makes an amendment so as to provide that the additional fee may be reduced in certain cases.

There is also a package of changes to the General Fees Regulations relating to the levels of capital fees payable for applications for marketing authorizations, manufacturers' licences, wholesale dealers' licences, clinical trial certificates and export certificates; capital fees payable for variations and renewals of such authorizations, licences and certificates; periodic fees payable in connection with the holding of certain authorizations and licences; and the fees payable in connection with site inspections (regulation 5(9) and the Schedule to these Regulations). Fees have been increased by approximately 8%.

A Regulatory Impact Assessment in relation to these Regulations has been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines Control Agency, Room 16-106, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

STATUTORY INSTRUMENTS

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