

**2004 No. 666**

**FEES AND CHARGES  
MEDICINES**

**The Medicines for Human Use and Medical Devices  
(Fees Amendments) Regulations 2004**

*Made* - - - - - *10th March 2004*

*Laid before Parliament* *10th March 2004*

*Coming into force* - - *1st April 2004*

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, the Department of Health, Social Services and Public Safety and the Department 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) 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 Amendments) Regulations 2004 and shall come into force on 1st April 2004.

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(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); see therefore section 1(1) of the 1968 Act, as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, by article 5 of, and the Schedule to, S.I. 1999/3142, and by article 5(1) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794, 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, by virtue of articles 2(1) of, and paragraph 1 of the Schedule to, S.I. 1999/3142 and articles 3(1)(c) and (7) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794; and in the case of the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, by virtue of the powers vested in the Ministers in charge of those Departments by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47) which may now be exercised by the Departments by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c. 1); the Departments were renamed by virtue of Article 3(4) and (6) of S.I. 1999/283 (N.I. 1).

(f) 1968 c. 67; section 129(6) was extended by section 1(3)(b) of the Medicines Act 1971.

(2) In these Regulations—

“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); and

“the Homoeopathic Products Regulations” means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(c).

### **Amendment of the Homoeopathic Products Regulations**

2.—(1) The Homoeopathic Products Regulations are amended as follows.

(2) In regulation 14(d) (fees for variations of certificates)—

- (a) in paragraph (2)(a), for “£216” substitute “£218”;
- (b) in paragraph (2)(b)(i), for “£216” substitute “£218”;
- (c) in paragraph (2)(b)(ii), for “£216” substitute “£218”;
- (d) in paragraph (2)(b)(iii), for “£108” substitute “£110”; and
- (e) in paragraph (2)(b)(iv), for “£54” substitute “£55”.

(3) In regulation 15(1)(e) (fees payable by holders of certificates), for “£14” substitute “£15”.

(4) In the Table in Schedule 2(f) (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 “£132” substitute “£134”,
  - (ii) for “£397” substitute “£402”, and
  - (iii) for “£656” substitute “£664”; and
- (b) in column (3) (fees for other applications)—
  - (i) for “£326” substitute “£330”,
  - (ii) for “£585” substitute “£592”, and
  - (iii) for “£859” substitute “£869”.

### **Amendment of regulation 3 of the Devices Regulations**

3. In regulation 3 of the Devices Regulations(g) (fees)—

- (a) in paragraph (1)(a), for “£3,533” substitute “£3,575”;
- (b) in paragraph (1)(b), for “£8,234” substitute “£8,333”;
- (c) in paragraph (2)(a), for “£699” substitute “£707”;
- (d) in paragraph (2)(b), for “£1,955” substitute “£1,978”;
- (e) in paragraph (3)(a), for “£3,533” substitute “£3,575”;
- (f) in paragraph (3)(b), for “£8,234” substitute “£8,333”;
- (g) in paragraph (4)(a), for “£699” substitute “£707”;
- (h) in paragraph (4)(b), for “£1,955” substitute “£1,978”;
- (i) in paragraph (5)(a), for “£36,126” substitute “£36,560”; and
- (j) in paragraph (5)(b), for “£8,969” substitute “£9,077”.

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(a) S.I. 1995/449; as amended by S.I. 1998/574, 1999/566, 2000/592, 2001/795, 2002/236 and 542, and 2003/625.

(b) S.I. 1995/1116; as amended by S.I. 1996/683, 1998/574, 1999/566, 2000/592 and 3031, 2001/795, 2002/236 and 542, and 2003/625 and 2321.

(c) S.I. 1994/105; as amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2000/592, 2001/795, 2002/236 and 542, and 2003/625 and 2321.

(d) As amended by regulation 2(2) of S.I. 2003/625.

(e) As amended by regulation 2(3) of S.I. 2003/625.

(f) As amended by regulation 2(4) of S.I. 2003/625.

(g) As amended by regulation 3 of S.I. 2003/625.

## **Amendment of regulation 2 of the General Fees Regulations**

4. In regulation 2 of the General Fees Regulations (interpretation), in paragraph (1)—
- (a) after the definition of “concerned member State”(a) insert the following definition—  
““contract laboratory” means a laboratory carrying out the tests specified in paragraph 5A(2) of Schedule 2 or paragraph 8(3)(a) of Schedule 3 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(b) on behalf of a holder of a manufacturer’s licence or a wholesale dealer’s licence, pursuant to Article 20(b) of the 2001 Directive;”;
  - (b) after the definition of “medicinal product” insert the following definition—  
““operator”, in relation to a contract laboratory, means the person having control of the contract laboratory;”;
  - (c) after the definition of “parallel import licence”(c) insert the following definition—  
““penalty fee” means a fee payable under regulation 18A;”.

## **Amendment of Part IA of the General Fees Regulations**

5.—(1) Part IA of the General Fees Regulations(d) (capital fees for pre-application meetings) is amended as follows.

- (2) In regulation 3A—
- (a) after the definition of “EC marketing authorization” insert the following definitions—  
““pharmacovigilance advice” means advice, other than scientific advice, which falls within one or more of the descriptions specified in paragraphs (a) and (b)—  
(a) the advice is in connection with an application for an EC marketing authorization, or is given with a view to a person making such an application, and relates to—  
(i) the obligations that would relate to the holder of such an authorization by virtue of Title IX of the 2001 Directive or Chapter 3 of Title II of Council Regulation (EEC) No. 2309/93, or  
(ii) a post-authorization safety study protocol,  
(b) the advice is given to the holder of a United Kingdom marketing authorization or a Community marketing authorization and relates to—  
(i) compliance with the obligations that relate to him by virtue of Title IX of the 2001 Directive or Chapter 3 of Title II of Council Regulation (EEC) No. 2309/93, or  
(ii) a post-authorization safety study protocol;  
“post-authorization safety study protocol” means a document that describes the objectives, design, methodology, statistical considerations and organisation of a post-authorization safety study;  
“product range” means one or more medicinal products containing the same active substance in relation to which the same person holds more than one EC marketing authorization;”;
  - (b) after the definition of “quality development” insert the following definition—  
““regulatory advice” means advice, other than scientific advice, in relation to the requirements of the 2001 Directive or Council Regulation (EEC) No. 2309/93 and which falls within one or more of the descriptions specified in paragraphs (a) to (c)—  
(a) the advice is in connection with a change to the dates for renewal of one or more EC marketing authorizations relating to a product range pursuant to Article 24 of the 2001 Directive,  
(b) the advice is in connection with—  
(i) a referral pursuant to Article 30, 31 or 36 of the 2001 Directive, or  
(ii) the procedure referred to in Article 35(2) of the 2001 Directive,  
in relation to a product range, or

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(a) The definition of “concerned member State” was inserted by regulation 2 of S.I. 2000/3031.

(b) S.I. 1971/972; relevant amending instruments are S.I. 1977/1053 and 1992/2846.

(c) The definition of “parallel import licence” was inserted by regulation 5(1)(c) of S.I. 2001/795.

(d) Part IA was inserted by regulation 4(3) of S.I. 2003/625 and amended by regulation 9 of S.I. 2003/2321.

- (c) the advice is given to a person with a view to him making—
  - (i) an application for the variation or renewal of one or more EC marketing authorizations, or
  - (ii) an application to amend the time periods for submitting Periodic Safety Update Reports under Article 104(6) of the 2001 Directive, in relation to a product range.”.

(3) After regulation 3B, insert the following regulations—

**“3BA.** Subject to regulation 19, where the licensing authority holds a meeting with the holder of a marketing authorization for the purpose of providing advice to him before the publication of advertising of a medicinal product by his undertaking on whether that advertising conforms to the requirements of Title VIII of the 2001 Directive, there shall be payable by the holder of that authorization a fee of £1,346.

**3BB.—**(1) Subject to regulation 19, where the licensing authority holds a meeting with a person for the purpose of providing pharmacovigilance advice to that person, there shall be payable by that person—

- (a) in a case where the time taken by the licensing authority to prepare for and attend the meeting is more than six hours, a fee of £1,690,
- (b) in any other case, a fee of £1,346.

(2) The time taken by the licensing authority for the purposes of paragraph (1) shall be the aggregate of times spent by each individual engaged in preparing for or attending the meeting on behalf of the authority.

**3BC.** Subject to regulation 19, where the licensing authority holds a meeting with the holder of one or more marketing authorizations for the purpose of providing advice to that person on proposed changes to the labelling or the package leaflets of the medicinal products to which those authorizations relate, there shall be payable by that person a fee of £1,012.

**3BD.** Subject to regulation 19, where the licensing authority holds a meeting with the holder of a marketing authorization for the purpose of providing regulatory advice to that person, there shall be payable by that person a fee of £1,346.”.

#### **Amendment of regulation 4 of the General Fees Regulations**

**6.** In regulation 4 of the General Fees Regulations (applications for authorizations, licences or certificates), after “paragraphs 2 to 6 of that Schedule”, insert—

“,  
except that where such an inspection is made of a contract laboratory the fee in respect of that inspection shall be payable by the operator of that laboratory”.

#### **Amendment of regulation 5 of the General Fees Regulations**

**7.** In regulation 5 of the General Fees Regulations (inspections in connection with multiple applications for authorizations or licences) after “an inspection mentioned in regulation 4(b)”, insert “, except for an inspection of a contract laboratory,”.

#### **Amendment of regulation 7 of the General Fees Regulations**

**8.** In regulation 7 of the General Fees Regulations (variations of authorizations, licences or certificates),—

- (a) in paragraph (1) after “Subject to” insert “paragraph (3) and”; and
- (b) after paragraph (2) insert the following paragraph—

“(3) Where an inspection referred to in paragraph (2)(a) is an inspection of a contract laboratory, the fee in respect of that inspection shall be payable by the operator of that laboratory.”.

### **Amendment of regulation 8 of the General Fees Regulations**

9. In regulation 8 of the General Fees Regulations (inspections in connection with multiple applications for variations of authorizations and licences) after “an inspection”, insert “, except for an inspection of a contract laboratory,”.

### **Amendment of regulation 13 of the General Fees Regulations**

10. In regulation 13 of the General Fees Regulations (fees for inspections), in paragraph (2), after “holder of that licence”, insert “, except that where an inspection is made of a contract laboratory the fee shall be payable by the operator of that laboratory”.

### **Amendment of Part VII of the General Fees Regulations**

11. After regulation 18 (time for payment of periodic fees), insert the following regulations—

#### **“Penalty fees for late payment of periodic fees**

18A.—(1) Subject to paragraph (2), if a person has failed to pay a periodic fee, at the time it should have been paid by virtue of regulation 18, a penalty fee shall be payable by that person.

(2) A penalty fee is payable only if after 60 days following written notice from the licensing authority requiring payment of that fee, the fee remains unpaid.

(3) Subject to regulation 18B, the penalty fee shall be—

- (a) £100 where the total periodic fee unpaid by a person after 60 days following the notice referred to in paragraph (2) exceeds £200, or
- (b) £50 where the total periodic fee unpaid by a person after such period does not exceed £200.

(4) In paragraph (3), the “total periodic fee” means the aggregate of all the periodic fees payable by a person in connection with all the authorizations or licences held by that person.

18B. If the periodic fee and penalty fee under regulation 18A (“the outstanding amount”) have not been paid within 90 days following the written notice from the licensing authority, the amount of penalty fee payable shall be the amount specified in regulation 18A(3) plus £5 for each day of the period which—

- (a) begins with the day 90 days from the date of the written notice; and
- (b) ends with the day before that on which payment of the outstanding amount is actually made.

18C. The licensing authority may refund or waive payment of the penalty fee, or reduce the amount payable, where it is satisfied that the holder of the authorization or licence was not responsible for the failure to pay the periodic fee within the period specified in regulation 18A(2) or 18B.”

### **Amendment of Part I of Schedule 1 to the General Fees Regulations**

12. In Part I of Schedule 1 to the General Fees Regulations (interpretation), in paragraph (1)—

(a) in the definition of “complex application”, after sub-paragraph (b) insert the following sub-paragraph—

“(bb) the application is an application for a marketing authorization to which the first sub-paragraph of paragraph 3 of Part II of Annex I to the 2001 Directive applies;”;

(b) in the definition of “simple application”, in sub-paragraph (a), after “other than” insert “an application to which the first sub-paragraph of paragraph 3 of Part II of Annex I to the 2001 Directive applies or”.

## Amendment of Schedule 2 to the General Fees Regulations

13.—(1) Schedule 2 to the General Fees Regulations (fees for inspections) is amended as follows.

(2) In sub-paragraph (1) of paragraph 1—

(a) after the definition of “non-routine inspection” insert the following definition—

““principles of good laboratory practice” means—

(a) the principles of good laboratory practice set out in Schedule 1 to the Good Laboratory Practice Regulations 1999<sup>(a)</sup>, read with

(b) the revised guidance for the conduct of test facility inspections and study audits set out in Schedule 2 to those Regulations;”;

(b) in the definition of “principle or guideline of good manufacturing practice”<sup>(b)</sup>, for “Chapter II of Commission Directive 91/356/EEC<sup>(c)</sup> laying down the principles and guidelines of good manufacturing practice for medicinal products for human use” substitute “Commission Directive 2003/94/EC<sup>(d)</sup> laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use”.

(3) After paragraph 4, insert the following paragraph—

“4A.—(1) Subject to sub-paragraph (2), the fee payable in respect of an inspection of a contract laboratory pursuant to Article 20(b) and Article 111 of the 2001 Directive shall be—

(a) if the laboratory carries out only one type of analytical work, £2,000,

(b) if the laboratory carries out two types of analytical work, £3,000, and

(c) if the laboratory carries out three or more types of analytical work, £4,000.

(2) Where an inspection referred to in sub-paragraph (1) takes place at the same time as an inspection, by a person appointed by the Good Laboratory Practice Monitoring Authority under regulation 3(4) of the Good Laboratory Practice Regulations 1999, for the purposes of ascertaining whether a contract laboratory complies with the principles of good laboratory practice, the fee payable shall be—

(a) if the laboratory carries out only one type of analytical work, £500,

(b) if the laboratory carries out two types of analytical work, £1,250, and

(c) if the laboratory carries out three or more types of analytical work, £2,000.

(3) The types of analytical work referred to in sub-paragraphs (1) and (2) are—

(a) physico-chemical analysis,

(b) microbiological analysis including sterility testing,

(c) LAL endotoxin analysis, and

(d) rabbit pyrogen testing.”.

## Amendment of Schedule 5 to the General Fees Regulations

14. In Schedule 5 to the General Fees Regulations (waiver, reduction or refund of capital fees), in paragraph 1A<sup>(e)</sup>, after sub-paragraph (1) insert the following sub-paragraph—

“(1A) Where the licensing authority holds a meeting referred to in regulations 3BA to 3BD and that meeting was held at the request of the authority, any fee payable under those regulations in respect of that meeting may be waived.”.

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(a) S.I. 1999/3106.

(b) The definition of “principle or guideline of good manufacturing practice” was inserted by regulation 4(1) and (7)(a)(ii) of S.I. 2003/625.

(c) OJ No. L 193, 17.7.1991, p. 30.

(d) OJ No. L 262, 14.10.1993, p. 22.

(e) Paragraph 1A was inserted by regulation 13(1) and (2) of S.I. 2003/2321.

**Amendment of the General Fees Regulations**

**15.** 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

9th March 2004 *Warner*  
Parliamentary Under Secretary of State,  
Department of Health

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

8th March 2004 *D. C. Gowdy*  
Permanent Secretary,  
Department of Health, Social Services and Public Safety

Sealed with the Official Seal of the Department of Agriculture and Rural Development

9th March 2004 *Pat Toal*  
Permanent Secretary,  
Department of Agriculture and Rural Development

We consent,

10th March 2004 *Derek Twigg*  
*Nick Ainger*  
Two of the Lords Commissioners of Her Majesty's Treasury

**SCHEDULE**

Regulation 15

<i>Column (1)</i> <i>Provision in the</i> <i>General Regulations</i>	<i>Column (2)</i> <i>Subject matter</i>	<i>Column (3)</i> <i>Old amount</i>	<i>Column (4)</i> <i>New amount</i>
<b>Regulation 3B(a)</b>	<b>Capital fees for pre-application meetings</b>		
Paragraph (a)		£1,000	£1,012
Paragraph (b)		£1,330	£1,346
Paragraph (c)		£1,670	£1,690
Paragraph (d)		£2,000	£2,024
<b>Regulation 6</b>	<b>Applications for certificates by Exporters of medicinal products</b>		
Paragraph (1)(a)		£117	£118
Paragraph (1)(b)		£52	£53
Paragraph (1)(c)(i)		£52	£53
<b>Regulation 10</b>	<b>Renewal of clinical trial certificates</b>	£2,199	£2,225
<b>Regulation 11(1)</b>	<b>Renewals of certain manufacturer's licences</b>	£125	£127
<b>Part II of Schedule 1(b)</b>	<b>Capital fees for applications for authorizations, licences and certificates</b>		
In column 2 of the Table in paragraph 1(1)			
Entry 1(a)		£25,835	£25,690
Entry 1(b)		£55,441	£56,106
Entry 1(c)		£79,630	£80,586
Entry 2(a)		£15,392	£15,577
Entry 2(b)		£21,990	£22,254
Entry 3(a)		£5,640	£5,708
Entry 3(b)		£8,063	£8,160
Entry 4		£2,199	£2,225
Entry 5		£1,465	£1,483
Entry 6		£362	£366
Paragraph 1A(1)		£6,480	£6,558
Paragraph 4(4)(b)		£494	£500
Paragraph 5(1)(a)		£140	£142
Paragraph 5(1)(b)		£265	£268
Paragraph 5(1)(c)		£2,415	£2,444
Paragraph 6(1)		£949	£1,402
Paragraph 6(2)		£698	£600
Paragraph 6(4)		£306	£310
Paragraph 7		£17,215	£17,422
<b>Part IIA of Schedule 1(c)</b>	<b>Capital fees for assistance in obtaining marketing authorizations in other EEA states</b>		
Paragraph 2(a)(i)		£33,992	£34,400
Paragraph 2(a)(ii)		£22,328	£22,596
Paragraph 2(b)(i)		£8,748	£8,853
Paragraph 2(b)(ii)		£5,832	£5,902
Paragraph 2(c)(i)		£3,499	£3,541
Paragraph 2(c)(ii)		£2,916	£2,951
Paragraph 2(d)		£2,094	£2,119
<b>Part III of Schedule 1(d)</b>	<b>Capital fees for applications for variations of authorizations, licences and certificates</b>		
Paragraph 2(a)		£140	£142
Paragraph 2(aa)		£214	£224
Paragraph 2(b)		£494	£590
Paragraph 2(c)		£7,326	£6,672
Paragraph 2(cc)		£21,990	£22,254
Paragraph 2(d)		£6,480	£6,558
Paragraph 3(a)		£220	£222
Paragraph 3(aa)		£334	£442
Paragraph 3(b)		£598	£714

(a) Regulation 3B was inserted by regulation 4(1) and (3) of S.I. 2003/625 and amended by regulation 9 of S.I. 2003/2321.

(b) Paragraphs 1A and 4(4) of Part II of Schedule 1 were inserted by regulation 5(5) of S.I. 2002/542.

(c) Part IIA was inserted by regulation 6 of S.I. 2000/2031.

(d) Paragraphs 2(d), 59 and 15 of Part III of Schedule 1 were inserted, and paragraph 6(b) of that Part was substituted, by regulation 5(6) of S.I. 2002/542.



<i>Column (1)</i> <i>Provision in the</i> <i>General Regulations</i>	<i>Column (2)</i> <i>Subject matter</i>	<i>Column (3)</i> <i>Old amount</i>	<i>Column (4)</i> <i>New amount</i>
Paragraph 3(c)		£11,432	£11,568
Paragraph 3(d)		£30,738	£31,106
Paragraph 5A(1)		£494	£500
Paragraph 6(a)		£140	£142
Paragraph 6(b)		£6,480	£6,558
Paragraph 6(c)		£292	£296
Paragraph 7(a)		£132	£200
Paragraph 7(b)		£264	£400
Paragraph 8		£132	£200
Paragraph 9		£304	£378
Paragraph 10		£132	£200
Paragraph 11		£216	£218
Paragraph 15(a)(ii)		£494	£500
Paragraph 15(a)(iii)		£247	£250
Paragraph 15(b)(ii)		£247	£250
Part IIIA of Schedule 1(a)	Capital fees for assessment of labels and leaflets		
Paragraph 2(a)		£350	£319
Paragraph 2(b)		£270	£273
Part IV of Schedule 1(b)	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		
Paragraph 1(a)		£7,327	£7,415
Paragraph 1(b)		£598	£605
Paragraph 2(a)(ii)		£598	£605
Paragraph 2(b)(ii)		£299	£303
Schedule 2	Fees for inspections		
Paragraph 2(a)(i)		£2,291	£2,481
Paragraph 2(a)(ii)		£4,249	£4,601
Paragraph 2(a)(iii)		£5,132	£5,557
Paragraph 2(a)(iv)		£8,796	£9,525
Paragraph 2(b)(i)		£2,492	£2,698
Paragraph 2(b)(ii)		£5,132	£5,557
Paragraph 2(b)(iii)		£8,061	£8,729
Paragraph 2(b)(iv)		£14,659	£15,873
Paragraph 2(c)(i)		£879	£952
Paragraph 2(c)(ii)		£2,460	£2,664
Paragraph 2(c)(iii)		£3,677	£3,982
Paragraph 2(c)(iv)		£6,888	£7,459
Paragraph 2(cc)(i)		£1,500	£1,518
Paragraph 2(cc)(ii)		£4,000	£4,048
Paragraph 2(cc)(iii)		£7,500	£7,590
Paragraph 2(d)		£166	£168
Paragraph 5(1)		£461	£499
Paragraph 5(1)		£1,011	£1,095
In column 2 of the Table in paragraph 5(3)(c)			
Entry for "None"		£1,011	£1,023
Entry for "1 to 4"		£1,211	£1,226
Entry for "5 to 20"		£2,011	£2,035
Entry for "21 to 100"		£4,011	£4,059
Entry for "101 to 500"		£9,011	£9,119
Entry for "More than 500"		£16,011	£16,203
Paragraph 5A(a)(d)		£3,500	£3,542
Paragraph 5A(b)		£5,000	£5,060

(a) Part IIIA of Schedule 1 was inserted by regulation 4(1) and (6) of S.I. 2003/625.

(b) Part IV of Schedule 1 was inserted by regulation 5(7) of S.I. 2002/542.

(c) Paragraph 5(3) was inserted by regulation 4(1) and (7)(e)(ii) of S.I. 2003/625.

(d) Paragraph 5A was inserted by regulation 4(1) and (7)(f) of S.I. 2003/625.

<i>Column (1)</i> <i>Provision in the</i> <i>General Regulations</i>	<i>Column (2)</i> <i>Subject matter</i>	<i>Column (3)</i> <i>Old amount</i>	<i>Column (4)</i> <i>New amount</i>
Paragraph 5A(c)		£10,000	£10,120
Part III of Schedule 3	Periodic fees for marketing authorizations and licences		
In column 2 of the Table in paragraph 1			
Entry 1		£14,241	£14,768
Entry 2(a)		£5,863	£6,080
Entry 2(b)(i)		£1,467	£1,521
Entry 2(b)(ii)		£732	£759
Entry 2(b)(iii)		£238	£247
Entry 2(c)(i)		£642	£666
Entry 2(c)(ii)		£321	£333
Entry 2(c)(iii)		£119	£123
Entry 2(d)(i)		£265	£275
Entry 2(d)(ii)		£132	£137
Entry 2(d)(iii)		£58	£60
Entry 2(e)		£72	£75
Paragraph 2(a)		£326	£338
Paragraph 2(b)		£161	£167
Paragraph 2(c)		£68	£71
Paragraph 3(a)		£5,863	£6,080
Paragraph 3(b)		£3,959	£4,105
Paragraph 7		£293	£304
Paragraph 8(1)		£180	£187
Paragraph 8(2)		£108	£112

## 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 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 amends the Homoeopathic Products Regulations so as to increase the amounts of the fees payable for applications for, and variations of, certificates of registration and the fees payable by holders of certificates of registration. These increases average overall 3.7 per cent.

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(c) concerning medical devices. Regulation 3 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 3.7 per cent.

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. Regulations 4 to 14 of these Regulations amend those Regulations as follows.

Regulations 4(a) and (b), 6 to 10 and 13 make provision for fees for inspections of contract laboratories. Regulations 6 to 10 amend the provisions for fees for inspections so as to provide that when an inspection is made of a contract laboratory the fee for that inspection is payable by the operator of the laboratory. Regulation 13 introduces the new fee for inspections of contract laboratories.

Regulations 4(c) and 11 make provision for new penalty fees for late payment of periodic fees.

Regulation 5 amends regulation 3A of the General Fees Regulations and inserts new regulations to make provision for new fees for meetings at which the licensing authority provide pharmacovigilance, advertising, or regulatory advice, or advice on proposed changes to labelling or package leaflets, to holders of marketing authorizations or to potential applicants for a marketing authorization. Regulation 14 makes provision for the waiver of fees payable in connection with these meetings where the meeting has been held at the request of the licensing authority.

Regulation 12 amends the definition of a complex application in Part I of Schedule 1 to the General Fees Regulations to add a new category of complex application as a consequence of the adoption of Commission Directive 2003/63/EC(d), which amends Directive 2001/83/EC(e) by substituting a new Annex I setting out standards and protocols in respect of the testing of medicinal products for which applications for marketing authorization are made.

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; capital fees payable for pre-application meetings; periodic fees payable in connection with the holding of certain authorizations and licences; and the fees payable in connection with site inspections (regulation 15 and the Schedule to these Regulations). There have been adjustments to specific capital fees,

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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 169, 12.7.1993, p. 1; amended by Directive 98/79/EC (OJ No. L 331, 7.12.1998, p. 1).

(d) OJ No. L 159, 27.6.2003, p. 46.

(e) OJ No. L 311, 28.11.2001, p. 67.

some increases and three reductions, plus a general 1.2 per cent increase, which together represent an overall 3.7 per cent increase in capital fees. Periodic fees have been increased by 3.7 per cent.

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 and Healthcare products Regulatory Agency, Room 16-107, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

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