2003 No. 625

FEES AND CHARGES
MEDICINES

The Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2003

Made - - - - -	*11th March 2003*
Laid before Parliament	*11th March 2003*
Coming into force	
Except for the purposes of regulation 4(2), (3) and (5)(b)	*1st April 2003*
For the purposes of regulation 4(2), (3) and (5)(b)	*1st July 2003*

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:

(**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 article 2(1) of, and paragraph 1 of the Schedule to, S.I. 1999/3142 and article 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.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2003 and shall come into force—

(a) except for the purposes of regulation 4(2), (3) and (5)(b), on 1st April 2003; and

(b) for the purposes of regulation 4(2), (3) and (5)(b), on 1st July 2003.

(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 (1)(a), for "£103" substitute "£110";

(b) in paragraph (1)(b)(i), for "£103" substitute "£110";

(c) in paragraph (1)(b)(ii), for "£51.50" substitute "£55";

(d) in paragraph (2)(a), for "£200" substitute "£216";

(e) in paragraph (2)(b)(i), for "£200" substitute "£216";

(f) in paragraph (2)(b)(ii), for "£200" substitute "£216";

(g) in paragraph (2)(b)(iii), for "£100" substitute "£108"; and

(h) in paragraph (2)(b)(iv), for "£50" substitute "£54".

(3) In regulation 15(1) (**e**) (fees payable by holders of certificates), for "£13" substitute "£14".

(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 "£122" substitute "£132",

(ii) for "£368" substitute "£397", and

(iii) for "£607" substitute "£656"; and

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

(i) for "£302" substitute "£326",

(ii) for "£542" substitute "£585", and

(iii) for "£795" substitute "£859".

Amendment of regulation 3 of the Devices Regulations

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

(a) in paragraph (1)(a), for "£3,271" substitute "£3,533";

(b) in paragraph (1)(b), for "£7,264" substitute "£8,234";

(c) in paragraph (2)(a), for "£647" substitute "£699";

(d) in paragraph (2)(b), for "£1,810" substitute "£1,955";

(e) in paragraph (3)(a), for "£3,271" substitute "£3,533";

(f) in paragraph (3)(b), for "£7,264" substitute "£8,234";

(g) in paragraph (4)(a), for "£647" substitute "£699";

(**a**) S.I. 1995/449; amended by S.I.1998/574, 1999/566, 2000/592, 2001/795, 2002/236 and 542.
(**b**) S.I. 1995/1116; amended by S.I. 1996/683, 1998/574, 1999/566, 2000/592 and 3031, 2001/795 and 2002/236 and 542.
(**c**) S.I.1994/105; amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2000/592, 2001/795, 2002/236 and 542.
(**d**) As amended by regulation 2(3) of S.I. 2002/542.
(**e**) As amended by regulation 2(4) of S.I. 2002/542.
(**f**) As amended by regulation 2(5) of S.I. 2002/542.
(**g**) As amended by regulation 4 of S.I. 2002/542.

(h) in paragraph (4)(b), for "£1,810" substitute "£1,955";

(i) in paragraph (5)(a), for "£33,450" substitute "£36,126"; and

(j) in paragraph (5)(b), for "£8,305" substitute "£8,969".

Amendment of the General Fees Regulations

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

(2) In regulation 2(1), in the definition of "marketing authorization" after "means" insert ", except in regulation 3A".

(3) After Part I of the General Fees Regulations (general) insert the following Part—

"PART IA

CAPITAL FEES FOR PRE-APPLICATION MEETINGS

3A. In this Part—

"clinical development" means the conduct of studies of a medicinal product in human subjects in order to—

(a) discover or verify the effects of such a product,

(b) identify any adverse reaction to such a product, or

(c) study absorption, distribution, metabolism and excretion of such a product,

with the object of ascertaining the safety or efficacy of that product, in accordance with Part 4 of Annex I to the 2001 Directive(**a**);

"EC marketing authorization" means—

(a) a United Kingdom marketing authorization granted by the licensing authority under the 1994 Regulations,

(b) a marketing authorization granted by the competent authority of an EEA State other than the United Kingdom in accordance with the 2001 Directive, or

(c) a Community marketing authorization;

"quality development" means the chemical, pharmaceutical and biological testing necessary to demonstrate the quality of a relevant medicinal product, in accordance with Part 2 of Annex I to the 2001 Directive;

"scientific advice" means advice in connection with the quality, safety or clinical development for a relevant medicinal product;

"relevant medicinal product" means a medicinal product for human use to which the provisions of the 2001 Directive apply(**b**);

"safety development" means the toxicological and pharmacological testing necessary to demonstrate the safety of a relevant medicinal product, in accordance with Part 3 of Annex I to the 2001 Directive.

3B. Subject to regulation 19, where the licensing authority holds a meeting with a person for the purpose of providing scientific advice to that person with a view to him making an application for an EC marketing authorization, there shall be payable by that person—

(a) if the advice provided at that meeting consists of advice in connection with—

(i) quality development only, or

(ii) safety development only,

a fee of £1,000;

(b) if the advice provided at that meeting consists of advice in connection with—

(i) quality and safety development, or

(ii) clinical development only,

a fee of £1,330;

(**a**) *See* the definition of "the 2001 Directive" in regulation 2(1) as substituted by S.I. 2002/236.

(**b**) *See* Articles 2 and 3 of the Directive.

(c) if the advice provided at that meeting consists of advice in connection with—

(i) quality and clinical development, or

(ii) safety and clinical development,

a fee of £1,670; and

(d) if the advice provided at that meeting consists of advice in connection with quality, safety and clinical development, a fee of £2,000.

3C. Subject to regulation 19, all sums payable by way of fees under regulation 3B shall become payable within 14 days following written notice from the licensing authority requiring payment of those fees.".

(4) After Part III of the General Fees Regulations (capital fees for applications for variations of authorizations, licences or certificates and for associated inspections) insert the following Part—

"PART IIIA

CAPITAL FEES FOR ASSESSMENT OF LABELS AND LEAFLETS

9A. For the purposes of this Part and Part IIIA of Schedule 1, a "set of proposed changes" means a number of proposed changes to the labelling or package leaflet of a medicinal product, where—

(a) if there is more than one version of the labelling or package leaflet for that product, those changes all relate to the same version; and

(b) those changes are submitted to the licensing authority at the same time.

9B.—(1) Subject to paragraph (2) and regulation 19, where—

(a) a set of proposed changes to the labelling or the package leaflet of a medicinal product which is the subject of a United Kingdom marketing authorization (other than a parallel import licence) is submitted to the licensing authority in accordance with Article 61(3) of the 2001 Directive, or

(b) a set of proposed changes to the labelling or the package leaflet of a medicinal product which is the subject of a parallel import licence is submitted to the licensing authority,

there shall be payable by the holder of that authorization or licence the fee prescribed in Part IIIA of Schedule 1 in connection with that change.

(2) Paragraph (1) shall not apply where a change to the labelling or package leaflet of a medicinal product is proposed in connection with an application for the variation of the marketing authorization for that product.

9C. Subject to regulation 19, all sums payable by way of fees under regulation 9B(1) shall be payable at the time when the proposed changes are submitted to the licensing authority.".

(5) In regulation 16 (time for payment of capital fees in connection with applications or inspections), in paragraph (1)—

(a) after "6C" insert "or 9C"; and

(b) after "regulation" insert "3C,".

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

"PART IIIA

CAPITAL FEES FOR ASSESSMENT OF LABELS AND LEAFLETS

1. In this Part, "clinical particulars", in relation to a medicinal product, means the clinical particulars contained in the Summary of Product Characteristics for that product as specified in paragraph 5 of Article 11 of the 2001 Directive.

2. Subject to paragraph 3, the fee payable under regulation 9B(1) in connection with a set of proposed changes to the labelling or the package leaflet of a medicinal product shall be—

(a) in respect of a product which is the subject of a United Kingdom marketing authorization other than a parallel import licence, £350; and

(b) in respect of a product which is the subject of a parallel import licence, £270.

3.—(1) This paragraph applies where more than one set of proposed changes falling within regulation 9B(1) is submitted by the same marketing authorization holder at the same time and where—

(a) the sets of proposed changes consist of identical changes to the labelling or package leaflets of products with the same active ingredient or combination of ingredients, dosage form and clinical particulars; or

(b) the sets of proposed changes consist of identical changes to different versions of the labelling or package leaflet of the same product.

(2) Where this paragraph applies, the fee payable under regulation 9B(1) shall be—

(a) in connection with the first set of proposed changes considered by the licensing authority, the appropriate amount specified in paragraph 2; and

(b) in connection with each of the other sets of proposed changes, 50 per cent of that amount.".

(7) In Schedule 2 (fees for inspections)—

(a) in paragraph 1 (interpretation), in sub-paragraph (1)—

(i) before the definition of "major inspection" insert the following definition—

""exempt imported product" means a medicinal product, as defined in Article 1.2 of the 2001 Directive, to which paragraph 1 of Schedule 1 to the 1994 Regulations applies, which was not manufactured in the United Kingdom and in relation to which no marketing authorization has been granted;", and

(ii) after the definition of "minor inspection" insert the following definitions—

""new premises or facilities", in relation to an inspection at a site, means premises or facilities—

(a) which have not been specified in any application for the grant, variation or renewal of a manufacturer's licence, other than an application to which the inspection relates, or

(b) which have been so specified, provided that—

(i) no manufacturing or assembly operations have been carried out at those premises or facilities, or

(ii) no inspection has been made of those premises or facilities on or after the date on which manufacturing or assembly operations were first carried out at those premises or facilities;

"non-routine inspection" means an inspection at a site in connection with the grant, variation or renewal of a manufacturer's licence or during the currency of such a licence which—

(a) relates to new premises or facilities on that site, or plans for such premises or facilities,

(b) relates to a material alteration of any existing premises or facilities at that site, or plans for such an alteration, provided that if the alteration has been made prior to the inspection—

(i) no manufacturing or assembly operations have been carried out at those premises or facilities since the alteration, or

(ii) no inspection has been made of those premises or facilities on or after the date on which manufacturing or assembly operations were first carried out following that alteration, or

(c) is made to ascertain whether the holder of the licence is able to demonstrate compliance with—

(i) any principle or guideline of good manufacturing practice (but not all those principles and guidelines), or any individual requirement of such a principle or guideline; or

(ii) the "Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products" published by the European Commission in Volume 3 of its publication "The Rules Governing Medicinal Products in the European Union";

"principle or guideline of good manufacturing practice" means one of the principles and guidelines of good manufacturing practice set out in Chapter II of Commission Directive 91/356/EEC(**a**) laying down the principles and guidelines of good manufacturing practice for medicinal products for human use;";

(b) in paragraph 2—

(i) at the beginning of sub-paragraph (b) insert "except in the case of an inspection falling within sub-paragraph (cc)",

(ii) in sub-paragraph (c), for "(b) or (d)" substitute "(b), (cc) or (d)",

(iii) after sub-paragraph (c), insert the following paragraph—

"(cc) except in the case of an inspection falling within sub-paragraph (d), where the inspection is a non-routine inspection—

(i) if the time taken to make the inspection is not more than one day, £1,500,

(ii) if the time taken to make the inspection is more than one day but not more than 3 days, £4,000,

(iii) if the time taken to make the inspection is more than 3 days, £7,500; and"; and

(c) in paragraph 3, in sub-paragraph (1), after "any inspection at a site" insert "(other than a non-routine inspection)";

(d) in paragraph 4—

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

(ii) after sub-paragraph (2), insert the following sub-paragraph—

"(3) This paragraph shall not apply in respect of a non-routine inspection.";

(e) in paragraph 5—

(i) in sub-paragraph (1), at the beginning insert "Subject to paragraph (3),", and

(ii) after sub-paragraph (2), insert the following sub-paragraph—

"(3) In the case of an inspection of a site in connection with the variation or renewal of a wholesale dealer's licence which relates to exempt imported products or during the currency of such a licence, the fee payable shall be the fee specified in the entry in column 2 of the following Table corresponding to the number of such products imported under that licence in the period of 12 months before the inspection specified in column 1 of that Table—

Column 1 *Number of exempt imported products imported in previous 12 months*	*Column 2* *Fee payable*
None	£1,011
1 to 4	£1,211
5 to 20	£2,011
21 to 100	£4,011
101 to 500	£9,011
More than 500	£16,011

"; and

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

"**5A.** The fee payable in respect of an inspection at a site during the currency of a marketing authorization for the purposes of ascertaining whether the holder of that authorization has complied with the obligations relating to pharmacovigilance imposed on him by virtue of regulation 7(1) and (2) of the 1994 Regulations(**b**) shall be—

(a) if the holder of the marketing authorization holds less than 5 such authorizations, £3,500;

(b) if the holder of the marketing authorization holds 5 or more such authorizations, but less than 50, £5,000; and

(**a**) OJ No. L193, 17.7.91, p. 30.
(**b**) *See* the definition of "the 1994 Regulations" in regulation 2(1) of the General Fees Regulations.

(c) if the holder of the marketing authorization holds 50 or more such authorizations, £10,000.".

(8) In Schedule 5 (waiver, reduction or refund of capital fees)—

(a) paragraph 2 is renumbered as sub-paragraph (1) of that paragraph and after that sub-paragraph insert the following sub-paragraph—

"(2) Where, at the specific request of the licensing authority, a proposed change is submitted to the licensing authority as a consequence of new information having a bearing on the safe use of the product, the fee payable under regulation 9B(1) shall be refunded or, if it has not yet been paid, shall be waived."; and

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

"5A. Where the inspection of a site is a non-routine inspection within the meaning of Schedule 2 and the time taken to make that inspection is not more than 2 hours, the fee otherwise payable under these Regulations in respect of that inspection shall be waived.".

(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,
11th March 2003 Department of Health

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

D. C. Gowdy
Permanent Secretary,
4th March 2003 Department of Health, Social Services and Public Safety

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

P. J. Small
Permanent Secretary,
7th March 2003 Department of Agriculture and Rural Development

We consent,

Nick Ainger
Philip Woolas
10th March 2003 Two of the Lords Commissioners of Her Majesty's Treasury

SCHEDULE

Regulation 4(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 exporters of medicinal products		
Paragraph (1)(a)		£108	£117
Paragraph (1)(b)		£48	£52
Paragraph (1)(c)(i)		£48	£52
Paragraph (1)(c)(ii)		£24	£26
Regulation 10	Renewal of clinical trial certificates	£2,036	£2,199
Regulation 11(1)	Renewals of certain manufacturer's licences	£116	£125
Part II of Schedule 1(**a**)	Capital fees for applications for authorizations, licences and certificates		
In column 2 of the Table in paragraph 1(1)			
Entry 1(a)		£24,431	£25,835
Entry 1(b)		£52,260	£55,441
Entry 1(c)		£74,657	£79,630
Entry 2(a)		£14,252	£15,392
Entry 2(b)		£20,361	£21,990
Entry 3(a)		£5,222	£5,640
Entry 3(b)		£7,466	£8,063
Entry 4		£2,036	£2,199
Entry 5		£1,356	£1,465
Entry 6		£335	£362
Paragraph 1A(1)		£6,000	£6,480
Paragraph 4(4)(b)		£458	£494
Paragraph 5(1)(a)		£130	£140
Paragraph 5(1)(b)		£245	£265
Paragraph 5(1)(c)		£2,236	£2,415
Paragraph 6(1)		£879	£949
Paragraph 6(2)		£646	£698
Paragraph 6(4)		£283	£306
Paragraph 7		£15,940	£17,215
Part IIA of Schedule 1(**b**)	Capital fees for assistance in obtaining marketing authorizations in other EEA states		
Paragraph 2(a)(i)		£32,400	£33,992
Paragraph 2(a)(ii)		£21,600	£22,328
Paragraph 2(b)(i)		£8,100	£8,748
Paragraph 2(b)(ii)		£5,400	£5,832
Paragraph 2(c)(i)		£3,240	£3,499
Paragraph 2(c)(ii)		£2,700	£2,916
Paragraph 2(d)		£1,939	£2,094
Part III of Schedule 1(**c**)	Capital fees for applications for variations of authorizations, licences and certificates		
Paragraph 2(a)		£198	£214
Paragraph 2(b)		£458	£494
Paragraph 2(c)		£6,784	£7,326
Paragraph 2(d)		£6,000	£6,480
Paragraph 3(a)		£310	£334
Paragraph 3(b)		£554	£598
Paragraph 3(c)		£10,586	£11,432
Paragraph 5A(1)		£458	£494
Paragraph 6(a)		£130	£140
Paragraph 6(b)		£6,000	£6,480

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

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

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

Column (1) *Provision in the General Regulations*	*Column (2)* *Subject matter*	*Column (3)* *Old amount*	*Column (4)* *New amount*
Paragraph 6(c)		£270	£292
Paragraph 7(a)		£122	£132
Paragraph 7(b)		£245	£264
Paragraph 8		£122	£132
Paragraph 9		£282	£304
Paragraph 10		£122	£132
Paragraph 11		£200	£216
Paragraph 12		£103	£110
Paragraph 15(a)(ii)		£458	£494
Paragraph 15(a)(iii)		£229	£247
Paragraph 15(b)(ii)		£229	£247
Part IV of Schedule 1(**a**)	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)		£6,784	£7,327
Paragraph 1(b)		£554	£598
Paragraph 2(a)(ii)		£554	£598
Paragraph 2(b)(ii)		£277	£299
Schedule 2	Fees for inspections		
Paragraph 2(a)(i)		£2,121	£2,291
Paragraph 2(a)(ii)		£3,934	£4,249
Paragraph 2(a)(iii)		£4,752	£5,132
Paragraph 2(a)(iv)		£8,144	£8,796
Paragraph 2(b)(i)		£2,307	£2,492
Paragraph 2(b)(ii)		£4,752	£5,132
Paragraph 2(b)(iii)		£7,464	£8,061
Paragraph 2(b)(iv)		£13,573	£14,659
Paragraph 2(c)(i)		£814	£879
Paragraph 2(c)(ii)		£2,278	£2,460
Paragraph 2(c)(iii)		£3,405	£3,677
Paragraph 2(c)(iv)		£6,378	£6,888
Paragraph 2(d)		£154	£166
Paragraph 5(1)		£427	£461
Paragraph 5(1)		£936	£1,011
Part III of Schedule 3	Periodic fees for marketing authorizations and licences		
In column 2 of the Table in paragraph 1			
Entry 1		£13,186	£14,241
Entry 2(a)		£5,429	£5,863
Entry 2(b)(i)		£1,358	£1,467
Entry 2(b)(ii)		£678	£732
Entry 2(b)(iii)		£220	£238
Entry 2(c)(i)		£594	£642
Entry 2(c)(ii)		£297	£321
Entry 2(c)(iii)		£110	£119
Entry 2(d)(i)		£245	£265
Entry 2(d)(ii)		£122	£132
Entry 2(d)(iii)		£54	£58
Entry 2(e)		£67	£72
Paragraph 2(a)		£302	£326
Paragraph 2(b)		£149	£161
Paragraph 2(c)		£63	£68
Paragraph 3(a)		£5,429	£5,863
Paragraph 3(b)		£3,666	£3,959
Paragraph 7		£271	£293
Paragraph 8(1)		£167	£180
Paragraph 8(2)		£100	£108

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

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 8 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 8 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. Regulation 4 of these Regulations amend those Regulations as follows. Regulation 4(3) inserts a new Part IA of those Regulations, to make provision for fees in respect of meetings at which the licensing authority provides scientific advice to potential applicants for marketing authorizations; regulation 4(2) makes a consequential amendment. Regulation 4(4) and 4(6) insert new Part IIIA of, and new Part IIIA of Schedule 1 to, those Regulations, to make provision for fees for proposed changes to the labels and package leaflets of medicinal products submitted to the licensing authority by marketing authorization holders. Regulation 4(5) makes a consequential amendment. Regulation 4(7) amends Schedule 2 to those Regulations (fees for inspections) so as to make provision for fees for "non-routine inspections", inspections in connection with wholesale dealer's licences under which certain medicinal products which do not have marketing authorizations are imported ("exempt imported products") and inspections in connection with the pharmacovigilance obligations of marketing authorization holders. Regulation 4(8) provides for the circumstances in which the fees for some of those inspections may be refunded or waived.

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 4(9) and the Schedule to these Regulations). Fees have been increased by 3 to 8 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 Control Agency, Room 16-107, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

(**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).

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