STATUTORY INSTRUMENTS

2007 No. 803

FEES AND CHARGES
MEDICINES
CONSUMER PROTECTION

The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007

Made - - - -	*12th March 2007*
Laid before Parliament	*16th March 2007*
Coming into force	
for the purpose of regulation 14	*13th March 2007*
for all other purposes	*1st April 2007*

The Secretary of State for Health, the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, acting jointly, make the following Regulations in exercise of the powers conferred on them by section 1(1) and (2) of the Medicines Act 1971 [M1] or, as the case may be, the powers conferred by those provisions and now vested in them [M2].

In so far as these Regulations are not made under section 1(1) and (2) of the Medicines Act 1971, the Secretary of State makes these Regulations in exercise of the powers conferred on her by section 2(2) of the European Communities Act 1972 [M3] and section 56(1) and (2) of the Finance Act 1973 [M4]. The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to medicinal products [M5] and medical devices [M6].

The Treasury has consented to the making of these Regulations as required by section 1(1) of the Medicines Act 1971 and section 56(1) of the Finance Act 1973.

In accordance with section 129(6) of the Medicines Act 1968 [M7], the Secretary of State for Health, the Department of Health, Social Services and Public Safety Development and the Department of Agriculture and Rural Development have consulted with such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations.

Marginal Citations

M1 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 S.I. 1969/388; see therefore section 1(1) of the 1968 Act, as amended by Schedule 1 to S.I. 1969/388, 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.

M2 In the case of the Secretary of State, by virtue of article 2(1) of S.I. 1999/3142 and article 3(1)(c) and (7) of S.I. 2002/794. 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 Department 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).

M3 1972 c.68.

M4 1973 c.51.

M5 S.I. 1972/181.

M6 The Secretary of State was designated in relation to measures relating to active implantable medical devices in S.I. 1991/2289, and in relation to measures relating to medical devices other than active implantable medical devices in S.I. 1993/2661.

M7 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) (No.2) Regulations 2007 and shall come into force—

(a) for the purposes of regulation 14, on 13th March 2007; and

(b) for all other purposes, on 1st April 2007.

(2) In these Regulations, "the Medicines Fees Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995 .

Amendment of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994

2.—(1) The Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 are amended as follows.

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

(a) in paragraph (2)(a), for "£226" substitute "£237";

(b) in paragraph (2)(b)(i), for "£226" substitute "£237";

(c) in paragraph (2)(b)(ii), for "£226" substitute "£237";

(d) in paragraph (2)(b)(iii), for "£114" substitute "£120"; and

(e) in paragraph (2)(b)(iv), for "£57" substitute "£60".

(3) In regulation 15 (fees payable by holders of certificates), in paragraph (1), for "£15" substitute " £19 ".

(4) In the table in Schedule 2 (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 "£148" substitute " £155 ",

(ii) for "£444" substitute " £466 ",

(iii) in paragraph 3, for "£465" substitute " £488 ", and

(iv) for "£734" substitute " £770 "; and

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

(i) for "£365" substitute " £383 ",

(ii) for "£654" substitute " £686 ",

(iii) in paragraph 3, for "£608" substitute " £622 ", and

(iv) for "£960" substitute " £1,007 ".

(5) In Schedule 2A (fees for assistance in obtaining certificates of registration in other EEA States) , in paragraph 2—

(a) in sub-paragraph (a), for "£266" substitute " £279 "; and

(b) in sub-paragraph (b), for "£348" substitute "£365".

Amendment of Part I of the Medicines Fees Regulations

3. In Part I of the Medicines Fees Regulation (general), in regulation 2 (interpretation)—

(a) for the definition of "the 2001 Directive" substitute the following definition—

""the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use , as amended by—

(a) Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components ,

(b) Commission Directive 2003/63/EC amending Directive 2001/83/EC,

(c) Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC,

(d) Directive 2004/27/EC of the European Parliament and of the Council also amending Directive 2001/83/EC, and

(e) Regulation (EC) No. 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004;";

(b) after the definition of "EEA State" 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

(c) after the definition of "relevant fee period" substitute the following definition—

""special import notice" means a written notice given to the licensing authority in accordance with paragraph 7(2) of Schedule 2 to, or paragraph 3(2) of Schedule 4 to, the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 ;".

Amendment of Part IA of the Medicines Fees Regulations

4.—(1) Part IA of the Medicines Fees Regulations (capital fees for pre-application meetings) shall be amended as follows.

(2) In regulation 3A, in the definition of "pharmacovigilance advice"—

(a) in paragraph (a)—

(i) at the end of sub-paragraph (i), omit "or", and

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

"(ia) the pharmacovigilance and risk-management systems that the applicant would be required to introduce in accordance with Article 8(3)(ia) of the 2001 Directive;"; and

(b) in paragraph (b)—

(i) at the end of sub-paragraph (i), omit "or", and

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

"(ia) the pharmacovigilance and risk-management systems that he has introduced in accordance with Article 8(3)(ia) of the 2001 Directive;".

(3) In regulation 3B, for paragraph (b) substitute the following paragraphs—

"(b) if the advice provided at that meeting consists of advice in connection with clinical development only, a fee of £2,648;

(bb) if the advice provided at that meeting consists of advice in connection with quality and safety development only, a fee of £2,934;".

(4) After regulation 3BD, insert the following regulation—

"**3BE.**—(1) Where the licensing authority holds a meeting with a person who—

(a) is or is to be a sponsor of a clinical trial;

(b) manufactures medicinal products;

(c) is or is to be responsible for placing such products on the market; or

(d) acts on behalf of, or provides advice or assistance to, a person referred to in sub-paragraphs (a) to (c),

for the purpose of providing the advice specified in paragraph (2), there shall be payable by that person a fee of £4,335.

(2) The advice referred to in paragraph (1) is advice in relation to—

(a) scientific or regulatory issues relating to the development of a medicinal product or a type of medicinal product;

(b) the design of pharmaceutical or pre-clinical tests, or clinical trials, for a medicinal product or a type of medicinal product;

(c) the management of risks in relation to a medicinal product or a type of medicinal product which is under development, or is being marketed in the European Community; or

(d) other scientific or regulatory issues relating to a medicinal product or a type of medicinal product after an EC marketing authorization has been granted for that product or a product of that type.

(3) This regulation does not apply to a meeting for the purpose of providing only any advice specified in regulations 3B to 3BD.

(4) In this regulation—

(a) "medical device" has the same meaning as in Article 1(2)(a) of Directive 93/42/EEC;

(b) "Directive 93/42/EEC" means Council Directive 93/42/EEC concerning medical devices as amended by Directive 200/70/EC of the European Parliament and of

the Council amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma ;

(c) "medicinal product" includes a substance incorporated in a medical device which, if used separately, may be considered to be a medicinal product as defined in Article 1(2) of the 2001 Directive;

(d) "regulatory issues" means issues relating to the application of any Community instrument relating to EC marketing authorizations or to medical devices, or any enactment which implements such an instrument;

(e) "risks" means any risk relating to the quality, safety or efficacy of a medicinal product as regards patients' health or public health, or any risk of undesirable effects on the environment;

(f) "sponsor" shall be construed in accordance with regulation 3 of the Medicines for Human Use (Clinical Trials) Regulations 2004 ; and

(g) a reference to the development of a medicinal product or a type of medicinal product is a reference to development for the purposes of—

(i) obtaining an EC marketing authorization, or making a variation to an EC marketing authorization, for that product or a product of that type; or

(ii) obtaining an EC design-examination certificate within the meaning of paragraph 4.3 of Annex II to Directive 93/42/EEC or an EC type-examination certificate within the meaning of paragraph 5 of Annex III to that Directive, for a medical device incorporating that product or a product of that type.".

(5) In regulation 3C, for "regulation 3B" substitute " regulations 3B to 3BE ".

Amendment of Part VI of the Medicines Fees Regulations

5. In Part VI of the Medicines Fees Regulations (periodic fees for marketing authorizations and licences), in regulation 14A (periodic fees for clinical trial authorisations) —

(a) in paragraph (1), for "paragraphs (3) to (5)" substitute "paragraphs (4) and (5)"; and

(b) omit paragraph (3).

Amendment of Part VII of the Medicines Fees Regulations

6. In Part VII of the Medicines Fees Regulations (administration), in regulation 15 (payment of fees to Ministers), omit the words from "specified in section 1(1)(a)" to the end.

Amendment of Schedule 1 to the Medicines Fees Regulations

7.—(1) Schedule 1 to the Medicines Fees Regulations (capital fees for applications for, and variations to, marketing authorizations, licences and certificates) is amended as follows.

(2) In Part I (interpretation), in paragraph 1—

(a) in the definition of "complex application"—

(i) for "sub-paragraphs (a) to (o)" substitute " sub-paragraphs (a) to (r) ", and

(ii) after paragraph (o) insert—

"(p) an application where the sole or primary evidence for the safety and efficacy of the medicinal product consists of published scientific literature;

(q) the application is—

(i) for an extension of an existing marketing authorization which fulfils the conditions set out in Annex II to Commission Regulation (EC) No. 1084/2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State , and

(ii) includes the results of pre-clinical tests or clinical trials as specified in Article 8(3)(i) of the 2001 Directive;

(r) the application—

(i) is not an application in accordance with Article 10, 10a or 10c of the 2001 Directive, and

(ii) includes the results of pre-clinical tests or clinical trials as specified in Article 8(3)(i) of the 2001 Directive;";

(b) after the definition of "EC marketing authorization", insert the following definition—

""eCTD format" means the electronic format of the Common Technical Document referred to in the guidance published by the European Commission in Volume 2B of "The Rules Governing Medicinal Products in the European Union", referred to in paragraph (1) of the Introduction to Annex I to the 2001 Directive ;"; and

(c) after the definition of "major application", insert the following definition—

""the MHRA portal" means the internet-based hosted platform which enables persons to carry out business with the Medicines and Healthcare products Regulatory Agency of the Department of Health electronically, known as the "the MHRA Portal";".

(3) In Part II (capital fees for applications for authorizations, licences and certificates), in paragraph 1, for sub-paragraph (1) substitute—

"(1) Subject to paragraphs 1A, 2, 3, 4 and 4A, the fee payable under regulation 4(a) in connection with an application for a marketing authorization of a kind described in column 1 of the following table shall be—

(a) if—

(i) the application is made using the MHRA portal, and

(ii) the particulars and documents accompanying the application are presented in eCTD format,

the fee specified in the corresponding entry in column 2 of that table; or

(b) in any other case, the fee specified in the corresponding entry in column 3 of that table.

Fees for marketing authorization applications

Column 1 Kind of application	*Column 2 Fee payable if application is in eCTD format*	*Column 3 Fee payable in other cases*
1 Major application		
(a) in respect of an application relating to an orphan medicinal product to which point 6 of Part II of Annex 1 to the 2001 Directive applies	£28,494	£29,890

(b) which is a mutual recognition procedure incoming application	£61,959	£64,995
(c) which is a European reference product application	£61,959	£64,995
(d) which is a decentralised procedure application where the United Kingdom is a concerned Member State	£88,993	£93,249
(e) which is a decentralised procedure application where the United Kingdom is a reference Member State	£126,982	£133,204
(f) in any other case	£88,893	£93,249
2 Complex application		
(a) which is a mutual recognition procedure incoming application	£17,202	£18,045
(b) which is a European reference product application	£17,202	£18,045
(c) which is a decentralised procedure application where the United Kingdom is a concerned Member State	£24,576	£25,780
(d) which is a decentralised procedure application where the United Kingdom is a reference Member State	£34,353	£36,036
(e) in any other case	£24,576	£25,780
3 Standard application		
(a) which is a mutual recognition procedure incoming application	£6,304	£6,613
(b) which is a European reference product application	£6,304	£6,613
(c) which is a decentralised procedure application where the United Kingdom is a concerned Member State	£9,011	£9,453
(d) which is a decentralised procedure application where the United Kingdom is a reference Member State	£12,921	£13,554
(e) in any other case	£9,011	£9,453
4 Simple application		
(a) which is a decentralised procedure application where the United Kingdom is a concerned Member State	£2,457	£2,577
(b) in any other case	£2,457	£2,577
5 Application for a parallel import licence	*Not applicable*	£1,718
6 Change of ownership application	*Not applicable*	£424”

(4) In Part III (capital fees for applications for variations of authorizations, licences and certificates)—

(a) for paragraph 2 substitute the following paragraph—

"**2.** Subject to paragraphs 4 to 6 and 13 to 15, the fee payable under regulation 7(1) in connection with an application for a variation of a marketing authorization of a kind described in column 1 of the following table shall be—

(a) if—

(i) the application is made using the MHRA portal, and

(ii) the particulars and documents accompanying the application are presented in eCTD format,

the fee specified in the corresponding entry in column 2 of that table; or

(b) in any other case, the fee specified in the corresponding entry in column 3 of that table.

Fees for applications for variations of marketing authorizations

Column 1 Kind of application	*Column 2 Fee payable if application is in eCTD format*	*Column 3 Fee payable in other cases*
1 Application where, for the purposes of Commission Regulation (EC) No. 1084/2003, the United Kingdom is the reference Member State as defined in Article 3.4 of that Regulation		
(a) Type IA Application	£264	£276
(b) Type IB Application	£526	£552
(c) Type II Application	£852	£894
(d) Type II Complex Variation Application	£13,808	£14,484
(e) Extended Type II Complex Variation Application	£34,353	£36,036
2 Other variation applications		
(a) Type IA Application	£170	£178
(b) Type IB Application	£266	£280
(c) Type II Application	£704	£738
(d) Type II Complex Variation Application	£7,964	£8,354
(e) Extended Type II Complex Variation Application	£24,576	£25,780
(f) reclassification variation application	£8,206	£8,206"; and

(b) omit paragraph 3.

Amendment of Schedule 2 to the Medicines Fees Regulations

8. In Schedule 2 to the Medicines Fees Regulations (fees for inspections)—

(a) in paragraph 1, in sub-paragraph (1), omit the definition of "exempt imported product";

(b) in paragraph 2, omit sub-paragraph (f); and

(c) in paragraph 5—

(i) in sub-paragraph (1), omit "sub-paragraph (3) and", and

(ii) omit sub-paragraph (3).

Amendment of Schedule 3 to the Medicines Fees Regulations

9.—(1) Part III of Schedule 3 to the Medicines Fees Regulations (periodic fees for marketing authorizations and licences) is amended as follows.

(2) In the table in paragraph 1—

(a) in column (1), at the end insert the following entry—

"(h) Homoeopathic or anthroposophic product which is the subject of a licence of right";

(b) in column (2), at the end insert the following entry—

"2(h) £68".

(3) In paragraph 7, after sub-paragraph (2), insert the following sub-paragraph—

"(3) The fee payable under regulation 14(3) in connection with the holding of a manufacturer's licence which relates to the import of exempt imported products from a third country shall be the fee payable in accordance with sub-paragraph (1) and an additional amount calculated in accordance with paragraph 9B.".

(4) In paragraph 8, in sub-paragraph (1), for "paragraph 9" substitute " paragraphs 9 and 9A "

(5) After paragraph 9, insert the following paragraphs—

"**9A.** The fee payable under regulation 14(3) in connection with the holding of a wholesale dealer's licence which relates to exempt imported products shall be the fee payable in accordance with paragraphs 8 and 9 and an additional amount calculated in accordance with paragraph 9B.

Additional amount for manufacturer's licences and wholesale dealer's licences which relate to exempt imported products

9B.—(1) The additional amount referred to in paragraphs 7(3) and 9A in relation to any fee period shall be the fee specified in the entry in column 2 of the following table corresponding to the estimated number of special import notices for that fee period specified in column 1.

Column 1 Number of special import notices	*Column 2 Additional amount*
1 to 100	£100
101 to 1,000	£500
1,001 to 10,000	£5,000
10,001 to 25,000	£17,000
25,001 to 50,000	£37,000

50,001 to 100,000	£75,000
100,001 to 150,000	£125, 000
150,001 to 200,000	£175,000
200,001 or more	£250,000

(2) For the purposes of this paragraph, the estimated number of special import notices for any fee period shall be the number notified in writing to the licence holder by the licensing authority before the start of that fee period as the number of such notices which the authority estimate will be given by the holder during the fee period.".

Amendment of Schedule 6 to the Medicines Fees Regulations

10. In Schedule 6 to the Medicines Fees Regulations (adjustment, reduction or refund of periodic fees), after paragraph 1 insert the following paragraph—

"**1A.**—(1) This paragraph applies to periodic fees payable in connection with a manufacturer's licence or a wholesale dealer's licence which relates to exempt imported products.

(2) If during a fee period the number of special import notices given by a licence holder is greater than the estimated number notified by the licensing authority in accordance with paragraph 9B of Part III of Schedule 3, the periodic fee payable in relation to that period shall be increased by the difference, if any, between the amount payable in accordance with that paragraph and the amount which would have been payable if the estimated number notified by the licensing authority for that fee period had been the same as the actual number of notices given during that year.

(3) If during a fee period the number of special import notices given by a licence holder is less than the estimated number notified by the licensing authority in accordance with paragraph 9B of Part III of Schedule 3, the licensing authority shall refund the difference, if any, between the amount payable in accordance with that paragraph and the amount which would have been payable if the estimated number notified by the licensing authority for that fee period had been the same as the actual number of notices given during that year.".

Increase in fee amounts prescribed by the Medicines Fees Regulations

11. In each provision of the Medicines 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.

Amendment of the Medical Devices (Consultation Requirements) (Fees) Regulations 1995

12.—(1) The Medical Devices (Consultation Requirements) (Fees) Regulations 1995 are amended as follows.

(2) In regulation 1 (citation, commencement and interpretation), in paragraph (2)—

(a) for the definitions of "Annex II" and "Annex III" substitute the following definitions—

""Annex I", "Annex II" and "Annex III" mean respectively Annex I, Annex II and Annex III to the Directive;";

(b) in the definition of "competent body", for the words from "Directive 2001/83/EC" to the end substitute " the 2001 Directive ";

(c) after the definition of "the Directive" insert the following definition—

""the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, as amended by—

(a) Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components,

(b) Commission Directive 2003/63/EC amending Directive 2001/83/EC,

(c) Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC,

(d) Directive 2004/27/EC of the European Parliament and of the Council also amending Directive 2001/83/EC, and

(e) Regulation (EC) No. 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004;";

(d) omit the definition of "fee";

(e) in the definition of "manufacturing authorisation", for the words from "Directive 2001/83/EC" to the end substitute " the 2001 Directive "; and

(f) in the definition of "medicinal substance", for the words from "Directive 2001/83/EC" to the end substitute " the 2001 Directive ".

(3) In regulation 2 (circumstances in which a fee is payable), in paragraph (1), after "pay a fee" insert " specified by, or determined under, regulation 3 ".

(4) In regulation 3 (fees)—

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "£3,948" substitute "£4,141", and

(ii) in sub-paragraph (b), for "£9,202" substitute "£9,653";

(b) in paragraph (2)—

(i) in sub-paragraph (a), for "£781" substitute " £819 ", and

(ii) in sub-paragraph (b), for "£2,184" substitute "£2,291";

(c) in paragraph (3)—

(i) in sub-paragraph (a), for "£3,948" substitute "£4,141", and

(ii) in sub-paragraph (b), for "£9,262" substitute "£9,653";

(d) in paragraph (4)—

(i) in sub-paragraph (a), for "£781" substitute " £819 ", and

(ii) in sub-paragraph (b), for "£2,184" substitute "£2,291"; and

(e) in paragraph (5)—

(i) in sub-paragraph (a), for "£40,374" substitute "£42,352", and

(ii) in sub-paragraph (b), for "£10,024" substitute "£10,515".

(5) After regulation 3 insert the following regulation—

"**Fees for pre-consultation meetings**

3A.—(1) Where the Department of Health holds a meeting—

(a) with a person other than a notified body for the purpose of providing scientific advice to that person with a view to him making an application for an EC examination certificate in relation to a medical device incorporating a medicinal substance, or

(b) with a notified body for the purpose of providing scientific advice to that body with a view to that body consulting the Department in relation to an application for an EC examination certificate in relation to a medical device incorporating a medicinal substance,

that person or notified body shall pay the fee specified in paragraph (2).

(2) The fee payable shall be—

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

(i) quality development only, or

(i) safety development only,

£750;

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

(i) quality and safety development only, or

(i) clinical development only,

£950;

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

(i) quality and clinical development only, or

(i) safety and clinical development only,

£1,300;

(a) if the advice provided at that meeting consists of advice in connection with quality, safety and clinical development, £1,650.

(3) In this regulation—

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

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

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

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

with the object of ascertaining the safety or efficacy of that substance, as required to verify the safety and usefulness of the substance in accordance with paragraph 7.4 of Annex I;

"quality development" means the chemical, pharmaceutical and biological testing required in order to verify the quality of a medicinal substance in accordance with paragraph 7.4 of Annex I;

"safety development" means the toxicological and pharmacological testing required in order to verify the safety of a medicinal substance in accordance with paragraph 7.4 of Annex I; and

"scientific advice" means advice in connection with the quality, safety or clinical development for a medicinal substance incorporated, or to be incorporated, in a medical device.".

(6) For regulation 4 (payment and recovery of fees) substitute the following regulation—

"**Payment and recovery of fees**

4.—(1) Any fee payable in accordance with regulations 2 and 3 shall be paid to the Secretary of State not later than the day on which a notified body consults the competent body.

(2) Any fee payable in accordance with regulation 3A shall become payable within 14 days following written notice from the Department of Health requiring payment of that fee.

(3) All unpaid sums due on account of any fee payable under these Regulations shall be recoverable as debts due to the Crown.".

Amendment of the Medical Devices Regulations 2002

13.—(1) The Medical Devices Regulations 2002 shall be amended as follows.

(2) In regulation 54 (fees payable in connection with the designation etc of UK notified bodies)—

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "£650" substitute " £850 ", and

(ii) in sub-paragraph (b), for "£2,600" substitute "£3,400";

(b) in paragraph (2), for "£1,300" substitute "£1,700";

(c) in paragraph (3), for sub-paragraphs (a) to (c) substitute the following sub-paragraphs—

"(a) in respect of an initial inspection pursuant to regulation 45(7)(a), a fee of £4,200 plus the amounts specified in paragraph (3A);

(b) in respect of an inspection pursuant to regulation 45(7)(a), other than an initial inspection—

(i) if the inspection is for the purposes of deciding whether or not the body is one in respect of which the criteria set out in all three of the Annexes referred to in this paragraph are met, a fee of £6,800,

(ii) if the inspection is for the purpose of deciding whether or not the body is one in respect of which the criteria set out in only two of the three Annexes referred to in this paragraph are met, a fee of £5,100, or

(iii) if the inspection is for the purposes of deciding whether or not the body is one in respect of which the criteria set out in only one of the Annexes referred to in this paragraph are met, or for the purposes of deciding whether or not a body is capable of fulfilling the functions of an importing Party arising out of the Mutual Recognition Agreements which it needs to be able to fulfil, a fee of £3,400,

plus the amounts specified in paragraph (3A); and

(c) in respect of an inspection pursuant to regulation 45(7)(b), a fee of £3,400 plus the amounts specified in paragraph (3A).."; and

(d) after paragraph (3), insert the following paragraphs—

"(3A) Subject to paragraph (3B), the additional amounts payable in respect of an inspection referred to in paragraph (3) shall be—

(a) an amount for time spent by a member of staff undertaking a site visit at a rate—

(i) for the time spent on site, of £240 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and

(ii) for the time spent travelling to and from the site, of £67.10 per hour;

(b) the actual costs of travel, accommodation and subsistence; and

(c) out of pocket expenses.

(3B) Where the Secretary of State conducts an inspection referred to in paragraph (3)(a) on the same date and at the same premises as an inspection pursuant to regulation 48(7)(a)—

(a) the amount referred to in paragraph (3A)(3) shall include an amount for any time spent on site by a member of staff which is attributable to the conduct of the inspection pursuant to regulation 48(7)(a), at the rate referred to paragraph (3A)(a)(i); and

(b) the costs and expenses referred to in paragraph (3A)(b) and (c) shall include any additional costs and expenses attributable to the conduct of the inspection pursuant to regulation 48(7)(a).".

(3) In regulation 55 (fees payable in connection with the designation etc of EC conformity assessment bodies)—

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "£650" substitute " £850 ", and

(ii) in sub-paragraph (b), for "£2,600" substitute "£3,400";

(b) in paragraph (2), for "£1,300" substitute "£1,700";

(c) in paragraph (3)—

(i) at the beginning insert " Subject to paragraphs (3A) to (3C) ", and

(ii) for paragraphs (a) to (c) substitute the following sub-paragraphs—

"(a) in respect of an initial inspection pursuant to regulation 48(7)(a), other than an inspection referred to in sub-paragraph (c), fee of £4,200 plus the amounts specified in paragraph (3D);

(b) in respect of any other inspection pursuant to regulation 48(7)(a), other than an inspection referred to in sub-paragraph (c), a fee of £3,400 plus the amounts specified in paragraph (3D);

(c) in respect of an inspection pursuant to regulation 48(7)(a) conducted on the same date and at the same premises as an inspection pursuant to regulation 45(7), a fee of £1,700;

(d) in respect of an inspection pursuant to regulation 48(7)(b), a fee of £3,400 plus the amounts specified in paragraph (3D).''; and

(d) after paragraph (3), insert the following paragraphs—

"(3A) Where the Secretary of State conducts two or more inspections pursuant to regulation 48(7)(a) on the same date and at the same premises, other than inspections referred to in paragraph (3)(c), and one of the inspections is an initial inspection, the fee payable shall be £4,200 plus—

(a) £1,700 for each additional inspection; and

(b) the amounts specified in paragraph (3D).

(3B) Where the Secretary of State conducts two or more inspections pursuant to regulation 48(7)(a) on the same date and at the same premises, other than inspections referred to in paragraph (3)(c), and none of the inspections is an initial inspection, the fee payable shall be £3,400 plus—

(a) £1,700 for each additional inspection; and

(b) the amounts specified in paragraph (3D)

(3C) Where the Secretary of State conducts two or more inspections referred to in paragraph (3)(c) on the same date and at the same premises, the fee payable for the inspections pursuant to regulation 48(7)(a) shall be £1,700 for each inspection.

(3D) The additional amounts payable in respect of an inspection referred to in paragraphs (3) to (3B) shall be—

(a) an amount for time spent by a member of staff undertaking a site visit at a rate—

(i) for the time spent on site, of £240 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and

(ii) for the time spent travelling to and from the site, of £67.10 per hour;

(b) the actual costs of travel, accommodation and subsistence, and

(c) out of pocket expenses.".

(4) In regulation 56 (fees payable in relation to clinical investigations), in paragraph (1)—

(a) in sub-paragraph (a)—

(i) in sub-paragraph (i), for "£1,600" substitute "£1,800", and

(ii) in sub-paragraph (ii), for "£2,100" substitute "£2,400"; and

(b) in sub-paragraph (b)—

(i) in sub-paragraph (i), for "£2,200" substitute "£2,700", and

(ii) in sub-paragraph (ii), for "£3,000" substitute "£3,800".

Revocation of regulations

14. The Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2007 [M31] are hereby revoked.

Marginal Citations

M31 S.I. 2007/610

Signed by authority of the Secretary of State

Department of Health
8th March 2007

Hunt
Minister of State

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

L.S.
Department of Health, Social Services and Public Safety
8th March 2007

Andrew McCormick
Permanent Secretary

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

L.S.
Department of Agriculture and Rural Development
8th March 2007

Pat Toal
Permanent Secretary

We consent,

Dave Watts
Frank Roy
Two of the Lords Commissioners of Her Majesty's Treasury

12th March 2007

SCHEDULE Regulation 11

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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 Medicines (Products for Human Use—Fees) Regulations 1995 ("the Medicines Fees Regulations") and the Medical Devices Regulations 2002. These Regulations revoke and replace the Medicines for Human Use and Medical Devices (Fees Amendment) Regulations 2007 (see regulation 14).

The Homoeopathic Products Regulations implemented in part Council Directive 92/73/EEC[M35] (now repealed and re-enacted in Directive 2001/83/EC[M36]) 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. The overall average increase is 4.9%.

The Medicines Fees Regulations make provision for the fees payable under the Medicines Act 1971, and other fees payable in respect of Community obligations relating to marketing authorizations, licences and certificates in respect of medicinal products for human use. Regulations 3 to 10 of these Regulations amend the Medicines Fees Regulations so as to: amend the definition of "the 2001 Directive" to reflect the amendment of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products by Regulation (EC) No. 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use (regulation 3(a)); provide that the fee for pharmacovigilance advice meetings is payable in respect of meetings at which the licensing authority give advice on the pharmacovigilance and risk-management systems of marketing authorization holders (regulation 4(2)); provide for a new fee for meetings at which the licensing authority give advice on the development of medicinal products or post authorisation issues (regulation 4(4)); provide that a periodic fee is payable in respect of each clinical trial authorisation held by a clinical trial sponsor (regulation 5); make an amendment consequential on the amendments to the Medicines Act 1968 made by the Veterinary Medicines Regulations 2006 (regulation 6); extend the types of marketing authorization applications for which a "complex application" fee is payable (regulation 7(2)(a)); provide for increased fees for applications for marketing authorizations and variations to marketing authorizations where the application is not submitted electronically via the MHRA portal and using the European Community's electronic Common Technical Document format (regulation 7(2)(b) and (c), (3) and (4)); replace the inspection fees for manufacturers and wholesale dealers who import unlicensed medicinal products with new supplementary periodic fees based on the number of products imported each year (regulations 3(b) and (c) and 8 to 10); and introduce a periodic fee for homoeopathic and anthroposophic medicinal products which have a product licence of right (regulation 9(2)). Regulations 4(3) and 11 and the Schedule to these Regulations provide for increases in the fees payable under the Medicines Fees Regulations. The overall average increases are 88% for capital fees for pre-application meetings, 4.9% for capital

fees for applications for marketing authorizations etc, 5.5% for fees for inspections and 7% for periodic fees.

The Medical Devices (Consultation Requirements) (Fees) Regulations 1995 prescribe the fees which are payable where a notified body consults the competent body in accordance with Council Directive 93/42/EEC concerning medical devices [M37]. Regulation 12 of these Regulations amends the 1995 Regulations by increasing the amounts of the fees specified in regulation 3 of those Regulations (overall average increase of 4.9%) and provides for new fees in relation to meetings at which the Department of Health give advice in relation to medicinal substances incorporated in medical devices.

The Medical Devices Regulations 2002 contain the legislative measures necessary for the implementation of the European Community scheme for regulating the placing on the market and putting into service of medical devices, set out in Council Directive 90/385/EEC on the approximation of the laws of Member States relating to active implantable medical devices [M38], Council Directive 93/42/EEC concerning medical devices and Council Directive 98/79/EC on *in vitro* diagnostic devices [M39]. Regulation 13 of these Regulations amends regulations 54 to 56 of the Medical Devices Regulations 2002, which provide for the fees payable in connection with the designation etc of UK notified bodies and EC conformity assessment bodies and the fees payable in relation to clinical investigation notices. The fees are increased (the overall average increase is 30%) and provision is made for reduced fees where the Secretary of State conducts two or more inspections, for the purposes of deciding whether a body meets the criteria for notified bodies or EC conformity assessment bodies, at the same premises on the same date.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ and copies have been placed in the libraries of both Houses of Parliament.

Status:
Point in time view as at 01/04/2007.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use and Medical Devices (Fees Amendments) (No.2) Regulations 2007.