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 U.K.

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 U.K.

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 U.K.

F1 **3.** . . . . . .

Textual Amendments

F1 Regs. 3-11 revoked (1.4.2008) by The Medicines (Products for Human Use-Fees) Regulations 2008 (S.I. 2008/552), regs. 1, 48(1), **Sch. 7** (with reg. 48(2))

Amendment of Part IA of the Medicines Fees Regulations U.K.

F1 **4.** . . . . . .

Textual Amendments

F1 Regs. 3-11 revoked (1.4.2008) by The Medicines (Products for Human Use-Fees) Regulations 2008 (S.I. 2008/552), regs. 1, 48(1), **Sch. 7** (with reg. 48(2))

Amendment of Part VI of the Medicines Fees Regulations U.K.

F1 **5.** . . . . . .

Textual Amendments

F1 Regs. 3-11 revoked (1.4.2008) by The Medicines (Products for Human Use-Fees) Regulations 2008 (S.I. 2008/552), regs. 1, 48(1), **Sch. 7** (with reg. 48(2))

Amendment of Part VII of the Medicines Fees Regulations U.K.

F1 **6.** . . . . . .

Textual Amendments

F1 Regs. 3-11 revoked (1.4.2008) by The Medicines (Products for Human Use-Fees) Regulations 2008 (S.I. 2008/552), regs. 1, 48(1), **Sch. 7** (with reg. 48(2))

Amendment of Schedule 1 to the Medicines Fees Regulations U.K.

F1**7.** . . . . . .

Textual Amendments

F1 Regs. 3-11 revoked (1.4.2008) by The Medicines (Products for Human Use-Fees) Regulations 2008 (S.I. 2008/552), regs. 1, 48(1), **Sch. 7** (with reg. 48(2))

Amendment of Schedule 2 to the Medicines Fees Regulations U.K.

F1**8.** . . . . . .

Textual Amendments

F1 Regs. 3-11 revoked (1.4.2008) by The Medicines (Products for Human Use-Fees) Regulations 2008 (S.I. 2008/552), regs. 1, 48(1), **Sch. 7** (with reg. 48(2))

Amendment of Schedule 3 to the Medicines Fees Regulations U.K.

F1**9.** . . . . . .

Textual Amendments

F1 Regs. 3-11 revoked (1.4.2008) by The Medicines (Products for Human Use-Fees) Regulations 2008 (S.I. 2008/552), regs. 1, 48(1), **Sch. 7** (with reg. 48(2))

Amendment of Schedule 6 to the Medicines Fees Regulations U.K.

F1**10.** . . . . . .

Textual Amendments

F1 Regs. 3-11 revoked (1.4.2008) by The Medicines (Products for Human Use-Fees) Regulations 2008 (S.I. 2008/552), regs. 1, 48(1), **Sch. 7** (with reg. 48(2))

Increase in fee amounts prescribed by the Medicines Fees Regulations U.K.

F1**11.** . . . . . .

Textual Amendments

F1 Regs. 3-11 revoked (1.4.2008) by The Medicines (Products for Human Use-Fees) Regulations 2008 (S.I. 2008/552), regs. 1, 48(1), **Sch. 7** (with reg. 48(2))

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

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 **U.K.**

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 U.K.

14. The Medicines for Human Use and Medical Devices (Fees Amendments) Regulations 2007 [M14] are hereby revoked.

Marginal Citations

M14 S.I. 2007/610

Signed by authority of the Secretary of State

Hunt
Department of Health — 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 — *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 — *Pat Toal*, Permanent Secretary

We consent,

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

[F2]SCHEDULE U.K.

Regulation 11

Textual Amendments

F2 Sch. revoked (1.4.2008) by The Medicines (Products for Human Use-Fees) Regulations 2008 (S.I. 2008/552), regs. 1, 48(1), **Sch. 7** (with reg. 48(2))

. . . . . .

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).

[M15M16]The Homoeopathic Products Regulations implemented in part Council Directive 92/73/EEC (now repealed and re-enacted in Directive 2001/83/EC) 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.

M17 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 . 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.

M18M19 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 , Council Directive 93/42/EEC concerning medical devices and Council Directive 98/79/EC on *in vitro* diagnostic devices . 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.

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.