STATUTORY INSTRUMENTS

2005 No. 2979

FEES AND CHARGES
MEDICINES

The Medicines for Human Use (Fees Amendments)(No. 2) Regulations 2005

Made - - - -	*26th October 2005*
Laid before Parliament	*26th October 2005*
Coming into force	
Except for the purposes of regulation 2(c), regulation 2(g) insofar as it inserts a definition of "Regulation (EC) No. 726/2004", and regulations 3(b) and (d)	*16th November 2005*
For the purposes of regulation 2(c), regulation 2(g) insofar as it inserts a definition of "Regulation (EC) No. 726/2004", and regulations 3(b) and (d)	*20th November 2005*

The Secretary of State, being a Minister designated for the purposes of section 2(2) of the European Communities Act 1972(**1**) in relation to medicinal products(**2**), in exercise of the powers conferred upon her by the said section 2(2), the Secretary of State, with the consent of the Treasury, in exercise of the powers conferred upon her by section 56(1) and (2) of the Finance Act 1973(**3**), 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(**4**), or, as the case may be, powers conferred by those provisions and now vested in them(**5**), make the following Regulations.

(**1**) 1972 c. 68.
(**2**) S.I.1972/1811.
(**3**) 1973 c. 51.
(**4**) 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

In accordance with section 129(6) of the Medicines Act 1968(**6**) they have consulted with such organisations as appear to them to be representative of interests likely to be substantially affected by the Regulations.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Fees Amendments) (No. 2) Regulations 2005 and shall come into force—

(a) except for the purposes of regulation 2(c), regulation 2(g) insofar as it inserts a definition of "Regulation (EC) No. 726/2004", and regulations 3(b) and (d), on 16th November 2005; and

(b) for the purposes of regulation 2(c), regulation 2(g) insofar as it inserts a definition of "Regulation (EC) No. 726/2004", and regulations 3(b) and (d), on 20th November 2005.

(2) In these Regulations "the General Fees Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995(**7**).

Amendment of regulation 2 of the General Fees Regulations

2. In regulation 2 of the General Fees Regulations (interpretation), in paragraph (1)—

(a) after the definition of "the 1994 Regulations" insert the following definition—

> ""API manufacturer" means a person, other than the holder of a manufacturer's licence, engaged in the manufacture or assembly of active substances used as starting materials in the manufacture of medicinal products;";

(b) in the definition of "change of ownership application"(**8**)—

(i) in paragraph (a), after sub-paragraph (ia) insert—

> "(ib) a traditional herbal registration for a medicinal product in respect of which another person holds a traditional herbal registration;",

(ii) in paragraph (b), after "manufacturing authorisation" insert ", traditional herbal registration", and

(iii) in paragraph (c), after "manufacturing authorisation" insert ", traditional herbal registration";

(c) in the definition of "Community marketing authorization" after "Council Regulation (EEC) No 2309/93"(**9**) insert "or Regulation (EC) No. 726/2004";

---

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.

(**5**) 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).

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

(**7**) S.I. 1995/1116; as amended by S.I. 1996/683, 1998/574, 1999/566, 2000/592 and 3031, 2001/795, 2002/236 and 542, 2003/625 and 2321, 2004/666 and 1157, and 2005/1124.

(**8**) The definition of "change of ownership application" was substituted by regulation 2 of S.I. 1996/683 and amended by regulation 2(2)(b) of S.I. 2004/1157.

(**9**) OJ No. L214, 24.08.93, p.1.

(d) in the definition of "the 2001 Directive"(**10**) after "as amended" insert "by 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(**11**), Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(**12**), Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use(**13**) and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(**14**)";

(e) for the definition of "EEA State"(**15**) substitute the following definition—

""EEA State" means a Member State, Norway, Iceland or Liechtenstein;";

(f) after the definition of "fee period" insert the following definitions—

""Herbal Regulations" means the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005(**16**);

"herbal substances" has the meaning given by Article 1(31) of the 2001 Directive;";

(g) after the definition of "product licence of right" insert the following definitions—

""Regulation (EC) No. 726/2004" means Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(**17**);

"traditional herbal medicinal product" has the meaning given by Article 1(29) of the 2001 Directive;

"traditional herbal registration" means a registration granted by the licensing authority under the Herbal Regulations;"; and

(h) for the definition of "variation" substitute the following definition—

""variation"—

(a) in relation to—

(i) a United Kingdom marketing authorization granted by the licensing authority under the 1994 Regulations; or

(ii) a product licence which has effect as such a marketing authorization by virtue of paragraph 1 of Schedule 6 (transitional provisions) to those Regulations;

means "variation to the terms of a marketing authorization" as defined in Article 3(1) of Commission Regulation (EC) No 1084/2003;

(b) in relation to a traditional herbal registration, means a variation of the provisions of a traditional herbal registration;".

(**10**) The definition of "the 2001 Directive" was inserted by regulation 16(a)(ii) of S.I. 2002/236 and amended by regulation 8(2)(a) of S.I. 2003/2321.
(**11**) OJ No. L33, 8.2.2003, p.30.
(**12**) OJ No. L159, 27.6.2003, p.46.
(**13**) OJ No. L136, 30.4.2004, p.85.
(**14**) OJ No. L136, 30.4.2004, p.34.
(**15**) The definition of "EEA State" was inserted by regulation 2(1)(a) of S.I. 2001/795.
(**16**) S.I. 2005/2750.
(**17**) OJ No. L136, 30.4.2004, p.1.

Amendment of regulation 3A of the General Fees Regulations

3. In regulation 3A of the General Fees Regulations(**18**)—

(a) in the definition of "clinical development", for "Part 4" substitute "Section 5 of Part I";

(b) in the definition of "pharmacovigilance advice" for "Council Regulation (EEC) No 2309/93", in both places those words appear, substitute "Regulation (EC) No. 726/2004";

(c) in the definition of "quality development", for "Part 2" substitute "Section 3 of Part I";

(d) in the definition of "regulatory advice" for "Council Regulation (EEC) No 2309/93" substitute "Regulation (EC) No. 726/2004"; and

(e) in the definition of "safety development", for "Part 3" substitute "Section 4 of Part I".

Amendment of Part II of the General Fees Regulations

4.—(1) Part II of the General Fees Regulations (capital fees for applications for authorizations, licences or certificates and for associated inspections) is amended as follows.

(2) In regulation 4 (applications for authorizations, licences or certificates) (**19**)—

(a) after "Community marketing authorization)" insert ", a traditional herbal registration";

(b) after "contract laboratory" insert "or a site used by an API manufacturer,"; and

(c) after "that laboratory" insert "or, as the case may be, that API manufacturer".

(3) In regulation 5(**20**) (inspections in connection with multiple applications for authorizations or licences)—

(a) after "contract laboratory" insert "or a site used by an API manufacturer"; and

(b) in sub-paragraph (a), after "marketing authorization" insert ", traditional herbal registration".

(4) After regulation 5 insert the following regulation—

"**Applications for copy certificates of good manufacturing practice**

5A. In connection with an application for a certified copy of an original certificate of good manufacturing practice issued pursuant to Article 111(5) of the 2001 Directive there shall be payable by the applicant a fee of £53.".

Amendment of regulation 6C of the General Fees Regulations

5. In regulation 6C of the General Fees Regulations (time for payment of fees under regulation 4B)(**21**), and in the heading of that regulation, for "4B" substitute "6B".

Amendment of Part III of the General Fees Regulations

6.—(1) Part III of the General Fees Regulations (capital fees for applications for variations of authorizations, licences or certificates and for associated inspections) is amended as follows.

(2) In regulation 7 (variations of authorizations, licences and certificates)—

(a) in paragraph (1)—

(i) for "paragraph (3)" substitute "paragraphs (3) and (4)", and

(**18**) Regulation 3A was inserted by regulation 4(3) of S.I. 2003/625 and amended by regulation 5(2) of S.I. 2004/666.
(**19**) Regulation 4 was amended by S.I. 2004/666 and 2004/1157.
(**20**) Regulation 5 was amended by S.I. 2004/666 and 2004/1157.
(**21**) Regulation 6C was inserted by regulation 3 of S.I. 2000/3031 and renumbered by regulation 5(2) of S.I. 2001/795.

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

"(aa) under regulation 6 of the Herbal Regulations for the variation of a traditional herbal registration;";

(b) in paragraph (3)(**22**), for "(2)(a)" insert "(2)(b)"; and

(c) after paragraph (3) insert the following paragraph—

"(4) Where an inspection referred to in paragraph (2)(b) is an inspection of a site used by an API manufacturer, the fee in respect of that inspection shall be payable by that API manufacturer.".

(3) In regulation 8 (inspections in connection with multiple applications for variations of authorizations and licences), in paragraph (1)(**23**)—

(a) after "contract laboratory" insert "or a site used by an API manufacturer"; and

(b) in sub-paragraph (a), after "marketing authorization" insert ", traditional herbal registration".

(4) In regulation 9 (applications for multiple variations)—

(a) in paragraph (1), after "marketing authorization" insert ", traditional herbal registration"; and

(b) in paragraph (2), after "marketing authorization" insert ", traditional herbal registration".

Amendment of regulation 12 of the General Fees Regulations

7. In regulation 12 of the General Fees Regulations (renewals in terms which are not identical to the existing authorization, licence or certificate)—

(a) after "Community marketing authorization)" insert ", a traditional herbal registration"; and

(b) for "authorization or licence", in both places those words appear, substitute "authorization, registration or licence".

Amendment of regulation 12A of the General Fees Regulations

8. In regulation 12A of the General Fees Regulations(**24**), in paragraph (2)(b) for "28(4)" substitute "28".

Amendment of Part V of the General Fees Regulations

9.—(1) Part V of the General Fees Regulations (fees for inspections made during the currency of a marketing authorization or licence) is amended as follows.

(2) In regulation 13 (fees for inspections)—

(a) in paragraph (1), after "marketing authorization" insert ", a traditional herbal registration";

(b) in paragraph (2)—

(i) after "contract laboratory" insert "or a site used by an API manufacturer,", and

(ii) after "that laboratory" insert ", or, as the case may be, that API manufacturer"; and

(c) in paragraph (3)—

(i) after "marketing authorization", in each place those words appear, insert ", traditional herbal registration", and

(**22**) Paragraph (3) was inserted by regulation 8(b) of S.I. 2004/666.
(**23**) Paragraph (1) was renumbered as such by regulation 4(4) of S.I. 2004/1157.
(**24**) Regulation 12A was inserted by regulation 5(3) of S.I. 2002/542.

(ii) after "the authorization" insert "or registration".

(3) In regulation 13A (fees for inspections relating to good clinical practice in clinical trials) (**25**), for "regulations 19 and 23" substitute "regulation 19".

Amendment of Part VI of the General Fees Regulations

10.—(1) Part VI of the General Fees Regulations (periodic fees for marketing authorizations and licences) is amended as follows.

(2) In regulation 14 (periodic fees)—

(a) in paragraph (1)—

(i) after "(4)" insert ", (4A)",

(ii) after "Community marketing authorization)" insert ", a traditional herbal registration", and

(iii) after "authorization", in the third and fourth places those words appear, insert ", registration";

(b) after paragraph (4) insert the following paragraph—

"(4A) No periodic fee shall be payable in respect of the fee period during which a traditional herbal registration is first granted except where a registration was granted pursuant to—

(a) a change of ownership application; or

(b) an application, made no later than three months after the expiry of a traditional herbal registration, which is for a traditional herbal registration containing identical provisions to those contained in the expired registration and which is made by the person who held the expired registration,

and, in each case, a periodic fee has not been paid in respect of that fee period in connection with the holding of a traditional herbal registration for the medicinal product to which the registration relates."; and

(c) in paragraph (5), after "authorization", in each place those words appear, insert ", registration".

(3) In regulation 14A (periodic fees for clinical trial authorisations)(**26**), in paragraph (1), for "regulations 19 and 23" substitute "regulation 19".

Amendment of regulation 19 of the General Fees Regulations

11. In regulation 19 of the General Fees Regulations (adjustment, waiver, reduction or refund of fees), in paragraph (1), for "authorization, authorisation or licence", in both places those words appear, substitute "authorization, registration, authorisation or licence".

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

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

(a) after the definition of "active ingredient" insert the following definition—

""active ingredient from a new source" means an active ingredient in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that active ingredient included in a medicinal product in

(**25**) Regulation 13A was inserted by regulation 6(3) of S.I. 2004/1157.
(**26**) Regulation 14A was inserted by regulation 7(1) of S.I. 2004/1157.

respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted;";

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

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

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

"(o) the application is an application for a marketing authorization to which Article 10(3) of the 2001 Directive applies;";

(c) after the definition of "complex application" insert the following definitions—

""complex registration application" means an application for a traditional herbal registration relating to a medicinal product containing an active ingredient that has not previously been included as an active ingredient in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted;

"decentralised procedure application" means a major application, a complex application, a standard application or a simple application for a marketing authorization for a medicinal product in respect of which at the time of the application—

(a) a marketing authorization has not been granted in any EEA State; and

(b) an application for a marketing authorization has been made in more than one EEA State pursuant to the procedure in Title III, Chapter 4 of the 2001 Directive;";

(d) omit the definition of "decentralised incoming application";

(e) after the definition of "EC marketing authorization"(**27**) insert the following definition—

""European reference product application" means an application for a marketing authorization to which the third sub-paragraph of Article 10(1) of the 2001 Directive applies;";

(f) in the definition of "major application" after "an application" insert "for a marketing authorization";

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

""mutual recognition procedure incoming application" means a major application, a complex application, or a standard application for a marketing authorization for a medicinal product in respect of which—

(a) a marketing authorization has already been granted in another EEA State; and

(b) recognition of that marketing authorization is sought from the licensing authority by way of the grant of a marketing authorization in the United Kingdom, pursuant to the procedure in Title III, Chapter 4 of the 2001 Directive;";

(h) for the definition of "new excipient" substitute the following definition—

"'new excipient means—

(a) except in Part II, paragraph 8 and Part III, any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product—

(i) which is intended to be administered by the same route of administration as the product in question; and

(**27**) The definition of "EC marketing authorization" was inserted by regulation 9(2)(a) of S.I. 2004/1157.

(ii) in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted,

except that in the case of a medicinal product intended to be administered orally, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Community) as an approved ingredient or additive in food or in a food product;

(b) in Part II, paragraph 8 and Part III, any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product which is intended to be administered by the same route of administration as the product in question and in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted, except that—

(i) in the case of a medicinal product intended to be administered orally, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Community) as an approved ingredient or additive in food or in a food product; and

(ii) in the case of a medicinal product intended for external use only, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Community) as an approved ingredient or additive in a cosmetic product;";

(i) after the definition of "Phase IV trial"(**28**) insert the following definitions—

""reduced registration application category I" means an application, other than a complex registration application, for a traditional herbal registration relating to a medicinal product which is presented in the form of a herbal tea;

"reduced registration application category II" means an application, other than a complex registration application, for a traditional herbal registration where the application falls within one of the descriptions specified in sub-paragraphs (a) to (d) as follows—

(a) the application relates to a medicinal product which is presented in the form of a herbal tincture;

(b) the application relates to a medicinal product which is presented in the form of an essential oil;

(c) the application relates to a medicinal product which is presented in the form of a fatty oil; or

(d) the application relates to a medicinal product which contains only herbal substances in a capsule;";

(j) in the definition of "simple application" for sub-paragraph (a) substitute the following sub-paragraph—

"(a) an application for a marketing authorization to which Article 10c of the 2001 Directive applies; or"; and

(k) after the definition of "standard application" insert the following definitions—

(**28**) The definition of "Phase IV trial" was inserted by regulation 9(2)(b) of S.I. 2004/1157.

""standard registration application" means any application for the grant of a traditional herbal registration which is not a complex registration application, a reduced registration application category I, a reduced registration application category II or a change of ownership application;

"TSE risk excipient from a new source" means an excipient which has been manufactured from raw materials of ruminant origin or which has had raw materials of ruminant origin used in its manufacture and in respect of which—

(a) the application names as manufacturer a manufacturer not previously named as the manufacturer of that excipient included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted; and

(b) no European Pharmacopoeia certificate of suitability covering the excipient has been submitted with the application;

"vitamin or mineral from a new source" means a vitamin or mineral in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that vitamin or mineral included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted .".

Amendment of Part II of Schedule 1 to the General Fees Regulations

13.—(1) Part II of Schedule 1 to the General Fees Regulations (capital fees for applications for authorizations, licences and certificates) is amended as follows.

(2) In paragraph 1, for the Table in sub-paragraph (1) substitute the following Table—

"**Table**

Column 1	*Column 2*
Kind of application	*Fee payable*
1 Major application	
(a) in respect of any application relating to an orphan medicinal product or a product to which point 6 of Part II of Annex 1 to the 2001 Directive applies	£25,802
(b) which is a mutual recognition procedure incoming application	£56,218
(c) which is a European reference product application	£56,218
(d) which is a decentralised procedure application where the United Kingdom is a concerned Member State	£80,698
(e) which is a decentralised procedure application where the United Kingdom is the reference Member State	£115,098

Column 1	*Column 2*
(f) in any other case	£80,698
2 Complex application	
(a) which is a mutual recognition procedure incoming application	£15,689
(b) which is a European reference product application	£15,689
(c) which is a decentralised procedure application where the United Kingdom is a concerned Member State	£22,366
(d) which is a decentralised procedure application where the United Kingdom is the reference Member State	£31,219
(e) in any other case	£22,366
3 Standard application	
(a) which is a mutual recognition procedure incoming application	£5,820
(b) which is a European reference product application	£5,820
(c) which is a decentralised procedure application where the United Kingdom is a concerned Member State	£8,272
(d) which is a decentralised procedure application where the United Kingdom is the reference Member State	£11,813
(e) in any other case	£8,272
4 Simple application	
(a) which is a decentralised procedure application where the United Kingdom is a concerned Member State	£2,337
(b) in any other case	£2,337
5 Application for a parallel import licence	£1,493
6 Change of ownership application	£366”

(3) In paragraph 3(1), in the definition of “joint development” omit “Medicines”.

(4) Paragraph 5 is amended as follows—

(a) after paragraph (1)(a) insert the following paragraph—

“(aa) in a case to which sub-paragraph (3) applies, £1,402;”; and

(b) after sub-paragraph (2) insert the following sub-paragraph—

"(3) This sub-paragraph applies to the case of an application for a manufacturer's licence which is limited solely to the import of medicinal products from third countries.".

(5) After paragraph 7 (clinical trial authorisations)(**29**) insert the following paragraph—

"**Traditional herbal registrations**

8.—(1) Subject to sub-paragraphs (3) to (6), the fee payable under regulation 4(a) in connection with an application for a traditional herbal registration of a kind described in Column 1 of the following Table shall be the fee specified in the corresponding entry in Column 2 of that Table—

Table

Column 1	*Column 2*
Kind of application	*Fee payable*
1 Complex registration application	
(a) in respect of a medicinal product containing a single active ingredient	£4,500
(b) in any other case	£6,750
2 Standard registration application	
(a) in respect of a medicinal product containing 3 or fewer active ingredients	£2,250
(b) in any other case	£3,375
3 Reduced registration application category II	
(a) in respect of a medicinal product containing 3 or fewer active ingredients	£750
(b) in any other case	£1125
4 Reduced registration application category I	
(a) in respect of a medicinal product containing 3 or fewer active ingredients	£500
(b) in any other case	£750
5 Change of ownership application	£366

(2) Each reference in sub-paragraphs (3) to (6) to an amount payable under sub-paragraph (1) in respect of an application refers to the amount payable under that sub-paragraph in respect of an application of the kind in question.

(3) Where an application relates to a medicinal product which contains one or more vitamins or minerals which are vitamins or minerals from a new source, there shall be payable in addition to the amount payable under sub-paragraph (1) in respect of that application—

(a) if European Pharmacopoeia certificates of suitability covering all the vitamins or minerals which are a vitamin or mineral from a new source have been submitted with the application, a fee of £1,000;

(**29**) Paragraph 7 was substituted by regulation 9(1)(3)(b) of S.I. 2004/1157.

(b) in any other case, a fee of £2,000.

(4) Where an application relates to a medicinal product which contains one or more new excipients, an amount of £6,672 shall be payable in addition to the amount payable under sub-paragraph (1) in respect of that application.

(5) Where an application relates to a medicinal product which contains one or more TSE risk excipients from a new source, an amount of £590 shall be payable in addition to the amount payable under sub-paragraph (1) in respect of that application.

(6) Where an application relates to a medicinal product which is a sterile medicinal product, an amount of £2,000 shall be payable in addition to the amount payable under sub-paragraph (1) in respect of that application.".

Amendment of Part III of Schedule 1 to the General Fees Regulations

14.—(1) Part III of Schedule 1 to the General Fees Regulations (capital fees for applications for variations of authorizations, licences and certificates) is amended as follows.

(2) In paragraph 1—

(a) before the definition of "Extended Type II Complex Variation Application"(**30**) insert the following definitions—

""administrative variation application" means an application by a traditional herbal registration holder to vary a traditional herbal registration where the variation applied for falls within one of the following sub-paragraphs—

(a) a change of either or both of the name and the address of the holder of the registration;

(b) a change of either or both of the name and the address of a manufacturer, assembler, storer or distributor named in the registration where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise, and any change of address does not involve a change of the site of manufacture, assembly or storage or of the site from which distribution takes place;

(c) the removal from the registration of details of one or more of the sites of manufacture, assembly or storage or of the sites from which distribution takes place;

"complex variation application" means an application by a traditional herbal registration holder to vary a traditional herbal registration which relates to a change in the formulation of a medicinal product comprising one or more of the following changes—

(a) a change in that product's active ingredients which involves the addition of one or more active ingredients which are active ingredients from a new source;

(b) a change in that product's excipients which involves the addition of one or more TSE risk excipients from a new source; or

(c) a change which involves the addition of one or more vitamins or minerals which are vitamins or minerals from a new source where no European Pharmacopoeia certificate of suitability covering those vitamins or minerals has been submitted with the application;";

(b) after the definition of "Extended Type II Complex Variation Application" insert the following definition—

(**30**) The definition of "Extended Type II Complex Variation Application" was inserted by regulation 11(2)(a) of S.I. 2003/2321.

""new excipient variation application" means an application, other than a complex variation application, by a traditional herbal registration holder to vary a traditional herbal registration which relates to a change in the formulation of the medicinal product to add a new excipient;"; and

(c) after the definition of "reclassification variation application"(**31**) insert the following definition—

""standard variation application" means an application by a traditional herbal registration holder to vary a traditional herbal registration which is not a complex variation application, a new excipient variation application or an administrative variation application;".

(3) In paragraph 7—

(a) in paragraph (a) omit "and"; and

(b) after paragraph (a) insert the following paragraph—

"(aa) in the case of a manufacturer's licence which is limited solely to the import of medicinal products from a third country, £378; and".

(4) After paragraph 11 (clinical trial authorisations) (**32**) insert the following paragraph—

"**Traditional herbal registrations**

11A. Subject to paragraph 13, the fee payable under regulation 7(1) in connection with an application for variation of a traditional herbal registration shall be—

(a) where the application is a standard variation application, £224;

(b) where the application is a complex variation application, £590;

(c) where the application is a new excipient variation application, £6,672; and

(d) where the application is an administrative variation application, £142.".

(5) In paragraph 13 (identical variations)—

(a) after "marketing authorization" insert ", a traditional herbal registration"; and

(b) for "a wholesale dealer's licence or a clinical trial certificate" substitute "or a wholesale dealer's licence".

Amendment of Part IIIA of Schedule 1 to the General Fees Regulations

15. In paragraph 1 of Part IIIA of Schedule 1 to the General Fees Regulations (capital fees for assessment of labels and leaflets)(**33**), for "5" substitute "4".

Amendment of Schedule 2 to the General Fees Regulations

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

(2) In paragraph 2—

(a) for "3 to 6" substitute "2A to 8";

(b) in sub-paragraph (a), for "(b) to (d)" substitute "(b) to (f)";

(c) in head (i) of sub-paragraph (a), for "£2,481" substitute "£2,534";

(d) in head (ii) of sub-paragraph (a), for "£4,601" substitute "£4,654";

(**31**) The definition of "reclassification variation application" was inserted by regulation 5(6)(a)(i) of S.I. 2002/542.
(**32**) Paragraph 11 was substituted by regulation 9(4)(c) of S.I. 2004/1157.
(**33**) Part IIIA was inserted by regulation 5(7) of S.I. 2002/542.

(e) in head (iii) of sub-paragraph (a), for "£5,557" substitute "£5,610";

(f) in head (iv) of sub-paragraph (a), for "£9,525" substitute "£9,578";

(g) in head (i) of sub-paragraph (b), for "£2,698" substitute "£2,751";

(h) in head (ii) of sub-paragraph (b), for "£5,557" substitute "£5,610";

(i) in head (iii) of sub-paragraph (b), for "£8,729" substitute "£8,782";

(j) in head (iv) of sub-paragraph (b), for "£15,873" substitute "£15,926";

(k) in head (i) of sub-paragraph (c), for "£952" substitute "£1,005";

(l) in head (ii) of sub-paragraph (c), for "£2,664" substitute "£2,717";

(m) in head (iii) of sub-paragraph (c), for "£3,982" substitute "£4,035";

(n) in head (iv) of sub-paragraph (c), for "£7,459" substitute "£7,512";

(o) in sub-paragraph (d), for "£168" substitute "£221"; and

(p) after sub-paragraph (d) insert the following sub-paragraphs—

"(e) except in the case of an inspection falling within sub-paragraph (f), where the site inspected is limited solely to the import of medicinal products from third countries, £1,095;

(f) where the site inspected relates to the import of exempt imported products from third countries, 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 to that site in the period of 12 months before the inspection specified in column 1 of that Table—

Column 1	*Column 2*
Number of exempt imported products imported in previous 12 months	*Fee payable*
None	£1,023
1 to 4	£1,226
5 to 20	£2,035
21 to 100	£4,059
101 to 500	£9,119
More than 500	£16,203"

(3) After paragraph 2, insert the following paragraph—

"**2A.** Subject to paragraphs 3, 4, 5D and 6, the fee payable in respect of an inspection of a site used by an API manufacturer pursuant to Article 111(1)(a) of the 2001 Directive shall be—

(a) in respect of a minor inspection, £2,534;

(b) in respect of a standard inspection, £4,654;

(c) in respect of a major inspection, £5,610; and

(d) in respect of a supersite inspection, £9,578.".

(4) In paragraph 5, in sub-paragraph (1) for "paragraph (3)" substitute "sub-paragraph (3) and paragraph 5C".

(5) After paragraph 5A(**34**), insert the following paragraphs—

"**5B.**—(1) Subject to paragraph 6, the fee payable in respect of an inspection of a site in connection with the grant, variation or renewal of a manufacturer's licence or during the currency of such a licence, where the site inspected is wholly concerned with the manufacture, assembly or import from a third country of traditional herbal medicinal products, shall be—

(a) if the time taken to make the inspection is not more than 3 hours, £800;

(b) if the time taken to make the inspection is more than 3 hours but not more than 1 day, £1,300; and

(c) if the time taken to make the inspection is more than 1 day, the amount calculated by multiplying the total number of days taken to make the inspection by £1,300.

(2) In calculating the number of days taken to make an inspection for the purposes of sub-paragraph (c), any part day shall be counted as a whole day.

5C.—(1) Subject to paragraph 6, the fee payable in respect of an inspection of a site in connection with the grant, variation or renewal of a wholesale dealer's licence or during the currency of such a licence, where the site inspected relates wholly to traditional herbal medicinal products, shall be—

(a) if the time taken to make the inspection is not more than 3 hours, £600;

(b) if the time taken to make the inspection is more than 3 hours but not more than 1 day, £1,100; and

(c) if the time taken to make the inspection is more than 1 day, the amount calculated by multiplying the total number of days taken to make the inspection by £1,100.

(2) In calculating the number of days taken to make an inspection for the purposes of sub-paragraph (c), any part day shall be counted as a whole day.

5D.—(1) Subject to paragraph 6, the fee payable in respect of an inspection of an API manufacturer pursuant to Article 111(1)(a) of the 2001 Directive, where the site inspected is wholly concerned with the manufacture or assembly of starting materials for use in the manufacture of traditional herbal medicinal products, shall be—

(a) if the time taken to make the inspection is not more than 3 hours, £600;

(b) if the time taken to make the inspection is more than 3 hours but not more than 1 day, £1,100; and

(c) if the time taken to make the inspection is more than 1 day, the amount calculated by multiplying the total number of days taken to make the inspection by £1,100.

(2) In calculating the number of days taken to make an inspection for the purposes of sub-paragraph (c), any part day shall be counted as a whole day.".

Amendment of Schedule 3 to the General Fees Regulations

17.—(1) Schedule 3 to the General Fees Regulations (periodic fees for licences) is amended as follows.

(2) In Part I of the Schedule (interpretation), in paragraph 1, in the definition of "homoeopathic medicinal product" omit "products," and "or compositions".

(3) In Part III of the Schedule (periodic fees for marketing authorizations and licences)—

(**34**) Paragraph 5A was inserted by regulation 4(7)(f) of S.I. 2003/625.

(a) for paragraph 7 substitute the following paragraph—

"**7.**—(1) The fee payable under regulation 14(3) in connection with the holding of a manufacturer's licence shall be—

(a) in the case of a manufacturer's licence which is limited solely to the import of medicinal products from a third country, £187; and

(b) in any other case, £304.

(2) The fee payable under regulation 14(3) in connection with the holding of a manufacturing authorisation shall be £304."; and

(b) after paragraph 10 (clinical trial authorisations)(**35**) insert the following paragraph—

"**Traditional herbal registrations**

11. The fee payable under regulation 14(3) in connection with the holding of a traditional herbal registration shall be £75.".

Amendment of Schedule 4 to the General Fees Regulations

18.—(1) Schedule 4 to the General Fees Regulations (time for payment of capital fees-applications made by small companies) is amended as follows.

(2) In paragraph 2 for "1(c)" substitute "1(f)".

(3) After paragraph 4A(**36**), insert the following paragraph—

"**4B.**—(1) In connection with an application for a traditional herbal registration, the fee payable under regulation 4(a) shall, if the applicant so requests in writing, be payable as to 50 per cent at the time of the application and as to 50 per cent 12 months after that time.

(2) In connection with a complex variation application or a new excipient variation application to vary a traditional herbal registration, the fee payable under regulation 7(1) shall, if the applicant so requests in writing, be payable as to 50 per cent at the time of the application and as to 50 per cent 12 months after that time.".

(4) In paragraph 6, after "marketing authorization" insert ", traditional herbal registration".

Amendment of Schedule 5 to the General Fees Regulations

19.—(1) Schedule 5 to the General Fees Regulations (waiver, reduction or refund of capital fees) is amended as follows.

(2) In paragraph 2B(**37**)—

(a) in paragraph (1)(b) omit "Medicines";

(b) in paragraph (2)(b) omit "Medicines";

(c) in paragraph (3)(b) omit "Medicines"; and

(d) in sub-paragraph (4) omit "Medicines".

(3) After paragraph 2C(**38**) insert the following paragraph—

(**35**) Paragraph 10 was inserted by regulation 11(b) of S.I. 2004/1157.
(**36**) Paragraph 4A was inserted by regulation 6 of S.I. 2000/2031 and amended by regulation 5(11) of S.I. 2001/795 and regulation 16(k) of S.I. 2002/236.
(**37**) Paragraph 2B was inserted by regulation 5(8) of S.I. 2002/542.
(**38**) Paragraph 2C was inserted by regulation 5 of S.I. 2005/1124.

"**2D.** Where at the specific written request of the licensing authority or in response to the imposition of an urgent safety restriction under regulation 8 of the Herbal Regulations, an application is made for the variation of a traditional herbal registration so as to—

(a) restrict any one or more of the indications, dosage or target population, or

(b) add a new contraindication or a warning or both of these,

as a consequence of new information having a bearing on the safe use of the product, the fee payable under regulation 7(1) shall be refunded or, if it has not yet been paid, shall be waived.".

(4) In paragraph 3—

(a) in sub-paragraph (1)—

(i) after "marketing authorization" insert "or traditional herbal registration, or", and

(ii) in paragraph (c), after "marketing authorizations" insert "or traditional herbal registrations"; and

(b) in sub-paragraph (3)—

(i) after "marketing authorization" insert "or traditional herbal registration, or", and

(ii) omit "Medicines".

(5) In sub-paragraph 4A(1)(**39**), after "marketing authorization" insert " or traditional herbal registration,".

Amendment of Schedule 6 to the General Fees Regulations

20. In paragraph 1 of Schedule 6 to the General Fees Regulations (adjustment, reduction or refund of periodic fees)—

(a) after "marketing authorization", in the first and second place these words appear, insert ", traditional herbal registration or licence"; and

(b) after "marketing authorization", in the third place these words appear, insert ", traditional herbal registration".

Signed by authority of the Secretary of State for Health

Jane Kennedy
Minister of State,
Department of Health

24th October 2005

(**39**) Paragraph 4A was inserted by regulation 7(4) of S.I. 2004/1157.

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

D Kenny
A senior Officer,
Department of Health, Social Services and Public Safety

24th October 2005

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

Pat Toal
Permanent Secretary,
Department of Agriculture and Rural Development

26th October 2005

We consent,

Tom Watson
Joan Ryan
Two of the Lords Commissioners of Her Majesty's Treasury

24th October 2005

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make further amendments to the Medicines (Products for Human Use—Fees) Regulations 1995 ("the General Fees Regulations").

The General 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 2 to 20 of these Regulations amend those Regulations as follows.

Directive 2004/24/EC(**40**) amended Directive 2001/83/EC(**41**) to introduce a new simplified registration procedure for the marketing of certain traditional herbal medicinal products for human use. Regulations 2(b), (f), (g) and (h), and provisions in regulations 4, 6, 7, 9 to 14, 16 and 17 introduce capital fees payable for applications for traditional herbal registrations and for variations of such registrations, periodic fees payable in connection with holding a traditional herbal registration, and fees payable in connection with site inspections of manufacturers and wholesale dealers of traditional herbal medicinal products (in regulation 16(5)). Regulation 18 provides for small companies (defined in regulation 17 of the General Fees Regulations) to request deferred payment of certain of these capital fees. Regulations 19 and 20 provide for these capital and periodic fees to be waived, reduced or refunded in certain circumstances.

Regulations 2(a) and (d), 4(4), 8 and 15, and provisions in regulations 4, 6, 9, 12, 13, 16 and 17 make changes necessitated by the amendment of Directive 2001/83/EC by Directive 2004/27/EC(**42**). Regulation 2(a), and provisions in regulations 4, 6, 9 and 16 provide for fees for inspections of API (active pharmaceutical ingredient) manufacturers. Regulations 4, 6 and 9 amend the provisions for fees for inspections so as to provide that when an inspection is made of an API manufacturer the fee for that inspection is payable by that API manufacturer. Regulation 16(3) introduces the new fee for inspections of API manufacturers. There is a separate fee provided for by regulation 16(5) for inspections of sites of API manufacturers where only starting materials for use in the manufacture of traditional herbal medicinal products are manufactured or assembled.

Regulations 13(4), 14(3), 16(2)(p) and 17(3) introduce separate capital fees payable for applications for manufacturer's licences where these licences are solely for import of medicinal products from third countries, i.e. countries outside the EU, and for variations of such licences, periodic fees payable in connection with holding a manufacturer's licence solely for import, and fees payable in connection with site inspections of sites wholly connected with import.

Regulation 4(4) introduces a fee for the issue of certified copies of certificates of good manufacturing practice. Original certificates will be issued to manufacturers at the end of a successful good manufacturing practice inspection and the fees charged for these inspections have been increased accordingly by £53 by regulation 16(2). In broad terms the percentage increase over the range of these inspection fees is from less than 1% to 31%.

(**40**) Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ No. L136, 30.4.2004, p.85.
(**41**) Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use, OJ L311, 28.11.2001, p 67.
(**42**) Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ No. L136, 30.4.2004, p.34.

Regulations 12 and 13 make provision for the capital fees to be charged for new types of marketing authorization application introduced by Directive 2004/27/EC; in particular, European reference product applications and decentralised procedure applications where the UK is either the reference Member State or a concerned Member State. The definition of a "complex application" is also amended as a consequence of the amendment by Directive 2004/27/EC of the types of applications for a marketing authorization that can be made for a "generic" product where reliance is placed on data submitted by a previous applicant for a marketing authorization. Generic applications that are required to be accompanied by the results of pre-clinical tests or clinical trials as specified in Article 10(3) of Directive 2001/83/EC (as amended by Directive 2004/27/EC) will be classified as "complex applications".

Regulations 8, 15 and 17(2) make minor consequential amendments.

Regulations 2(c) and part of 3 and the definition of "Regulation (EC) No. 726/2004" in regulation 2(g) are amendments consequential on Regulation (EC) No. 726/2004(**43**) which replaced Council Regulation (EEC) No 2309/93(**44**). Regulations 3(a), (c) and (e) are consequential to the amendment of Annex I to Directive 2001/83/EC by Commission Directive 2003/63/EC(**45**).

Regulation 13(3) and part of regulation 19 replace references to the Medicines Commission with references to the Commission on Human Medicines as a consequence of the Medicines (Advisory Bodies) Regulations 2005(**46**) which amend the Medicines Act 1968 to, amongst other things, abolish the Medicines Commission.

Regulations 5, 6(2)(b), 9(3), 10(3) and 14(5)(b) correct minor errors and omissions in the General Fees Regulations.

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

(**43**) Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ No. L136, 30.4.2004, p.1.
(**44**) OJ No. L214, 24.08.93, p.1.
(**45**) Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ No. L159, 27.6.2003, p.46.
(**46**) S.I. 2005/1094.