STATUTORY INSTRUMENTS

2006 No. 2125

FEES AND CHARGES
MEDICINES

The Medicines for Human Use (Fees Amendments) Regulations 2006

Made - - - -	*26th July 2006*
Laid before Parliament	*1st August 2006*
Coming into force - -	*1st September 2006*

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(**1**)or, as the case may be, the powers conferred by those provisions and now vested in them(**2**).

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(**3**) and section 56(1) and (2) of the Finance Act 1973(**4**). 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(**5**).

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(**6**), the Secretary of State for Health, the Department of Health, Social Services and Public Safety and the Department of Agriculture and

(**1**) 1971 c. 69; as amended by section 21 of the Health and Medicines Act 1988 (c. 49). By virtue of section 1(3) of the 1971 Act, expressions used in that section have the same meaning as in the Medicines Act 1968 (c. 67); see therefore section 1(1) of the 1968 Act, as amended by article 2(2) of, and Schedule 1 to, S.I.1969/388, by article 5 of, and the Schedule to, S.I. 1999/3142, and by article 5(1) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794, which contains a definition of "the Ministers" which is relevant to the powers being exercised in the making of these Regulations. See also regulation 9(12) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144), by virtue of which the references in section 1(1) and (2)(b) of the 1971 Act to a licence under Part II of the 1968 Act include reference to a marketing authorization under the 1994 Regulations.

(**2**) 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).

(**3**) 1972 c. 68.

(**4**) 1973 c. 51.

(**5**) S.I. 1972/181.

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

Rural Development have consulted with such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Fees Amendments) Regulations 2006 and shall come into force on 1st September 2006.

(2) In these Regulations—

"the General Fees Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995(**7**); and

"the Homoeopathic Regulations" means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**8**).

Amendment of regulation 2 of the of the General Fees Regulations

2.—(1) In regulation 2 of the General Fees Regulations (interpretation), after the definition of "medicinal product", insert the following definition—

""national homoeopathic product" has the same meaning as in regulation 4(1B) of the 1994 Regulations(**9**);".

Amendment of Schedule 1 to the General Fees Regulations

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

(2) In Part I (interpretation)—

(a) after the definition of "active ingredient from a new source" insert—

""certificate of registration" means a certificate for the purposes of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994;";

(b) in the definition of "new excipient"—

(i) in paragraph (a)(ii), after "of right)" insert ", a certificate of registration", and

(ii) in paragraph (b), after "of right)" insert ", a certificate of registration"; and

(c) for the definition of "TSE risk excipient from a new source" substitute—

""TSE risk ingredient from a new source" and "TSE risk excipient from a new source" mean an active ingredient or excipient, respectively, 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 ingredient or excipient included in a medicinal product in respect of which a marketing authorization (other than a product licence of right), a certificate of registration or a traditional herbal registration has previously been granted, and

(**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, 2005/1124 and 2979, and 2006/494.
(**8**) S.I. 1994/105; relevant amending instruments are S.I. 1996/482, 2005/2753 and 2006/494.
(**9**) ()S.I. 1994/3144; see the definition of "the 1994 Regulations" in regulation 2(1) of the General Fees Regulations. Regulation 4(1B) was inserted by S.I. 2006/1952.

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

(3) In Part II (capital fees for applications for authorizations, licences and certificates)—

(a) in paragraph 1(1), for "paragraphs 1A, 2, 3 and 4," substitute "paragraphs 1A, 2, 3, 4 and 4A,";

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

"**4A.**—(1) In connection with an application for a marketing authorization for a national homoeopathic product prepared from not more than 5 homoeopathic stocks, the fee payable under regulation 4(a) shall be the amount set out in Column (2) in the Table below opposite the description in Column (1) appropriate to that application.

(2) In connection with any other application for a marketing authorization for a national homoeopathic product, the fee payable under regulation 4(a) shall be the amount set out in Column (3) in the Table below opposite the description in Column (1) appropriate to that application.

(3) This paragraph does not apply to an application which is a mutual recognition procedure incoming application or a decentralised procedure application.

Table

Column (1) *Description of application*	Column (2) *Fees for applications in respect of products prepared from not more than 5 homoeopathic stocks*	Column (3) *Fees for other applications*
1 An application in respect of a product which is both prepared solely from repeat stocks and is of a repeat formulation	£480	£680
2 An application in respect of a product which is either— (a) prepared solely from repeat stocks; or (b) is of a repeat formulation	£752	£942
3 Any other application	£1,010	£1,219

(4) Each reference in sub-paragraphs (5) to (7) to an amount payable under sub-paragraph (1) or (2) in respect of an application refers to the amount payable under that sub-paragraph in respect of an application of the kind in question.

(5) Where an application relates to a national homoeopathic product which is manufactured using a method of sterilisation—

(a) not used in the manufacture of a medicinal product in respect of which a marketing authorization (other than a product licence of right), a certificate of registration or a traditional herbal registration has previously been granted, and

(b) not referred to in the European Pharmacopoeia or any national pharmacopoeia of a member State,

an amount of £2,000 shall be payable in addition to the amount payable under sub-paragraph (1) or (2) in respect of that application.

(6) Where an application relates to a national homoeopathic 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) or (2) in respect of that application.

(7) Where an application relates to a national homoeopathic product which contains one or more TSE risk ingredients or excipients from a new source, an amount of £590 shall be payable in addition to the amount payable under sub-paragraph (1) or (2) in respect of that application.

(8) In this paragraph—

"formulation" does not include the formulation of a homoeopathic stock;

"homoeopathic marketing authorization" means a marketing authorization granted by the licensing authority in respect of a national homoeopathic medicinal product;

"identical" means—

(a) in relation to the formulation of the product, identical as regards the requirements in respect of composition, preparation and testing, and

(b) in relation to a homoeopathic stock, identical as regards the source, composition and preparation of the stock and the test which it is required to undergo;

"product" includes a series of products each of which is prepared from identical homoeopathic stocks;

"repeat formulation" means—

(a) the formulation of a product which is identical to the formulation of another product—

(i) in respect of which the applicant holds a certificate of registration or a homoeopathic marketing authorization, or

(ii) to which the applicant has, by the holder of the certificate of registration or the homoeopathic marketing authorization which relates to it, been authorised in writing to make reference for the purposes of his application; or

(b) where more than one application is made by the same applicant on the same occasion in respect of products of identical formulations, for the purposes of the second and any subsequent of those applications which the licensing authority considers, the formulation of the product to which the first of those applications which is considered by the licensing authority relates; and

"repeat stock" means—

(a) a homoeopathic stock which is identical to another homoeopathic stock which is used in the preparation of a product—

(i) in respect of which the applicant holds a certificate of registration or a homoeopathic marketing authorization, or

(ii) in respect of which another person holds a certificate of registration or a homoeopathic marketing authorization to which, for the purposes of his application, the applicant has been authorised in writing to make reference by the person (or, if more than one, each of the persons)

who supplied information to the licensing authority in connection with the application for the marketing authorization which relates to that product.".

(4) In Part III (capital fees for applications for variations of authorizations, licences and certificates)(**10**)—

(a) in paragraph 1—

(i) after the definition of "new excipient variation application", insert the following definition—

""new indication variation application" means an application to vary a marketing authorization for a national homoeopathic product, so that product is indicated for a therapeutic use not previously covered by that authorization;"; and

(ii) after the definition of "standard variation", insert the following definition—

""standard variation application for a homoeopathic product" means an application for a variation of a marketing authorization for a national homoeopathic medicinal product which requires—

(a) the replacement of an excipient used in the manufacture of the product,

(b) the replacement of a reagent indirectly associated with the manufacturing process of the product or which disappears from that process with a comparable reagent,

(c) a change to the qualitative composition of the container or other form of packaging immediately in contact with the product,

(d) a change to the method of manufacture of a homoeopathic stock included in the product,

(e) a change to the specification of any reagent of excipient used in the manufacture of the product,

(f) a change to the finished product specification of the product,

(g) a change to the test procedure for any raw material used in the manufacture of the product,

(h) a change to the test procedure for the product,

(i) a change to the test procedure for the container or other form of packaging immediately in contact with the product,

(j) a change to comply with a supplement to the European Pharmacopoeia or any national pharmacopoeia of a member State,

(k) a change to the shape of the container in which the product may be placed on the market,

(l) an additional pack size in which the product may be placed on the market,

(n) a change to the approved storage conditions for the product,

(n) a change to the shelf life of an unopened container of the product after the container has been opened for the first time,

(o) a change to the dimensions of an approved dosage form of the product (for example, tablets), or

(**10**) Part III of Schedule 1 was amended by S.I.1996/683, 1998/574, 1999/566, 2000/592, 2001/795, 2002/236 and 542, 2003/625 and 2321, 2004/666 and 1157 and 2005/2979.

(p) a change following modification to the manufacturing authorization referred to in Article 40 of the 2001 Directive; and".

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

"**5B.** The fee payable under regulation 7(1) in connection with an application for a variation of a marketing authorization in respect of a national homoeopathic product shall be—

(a) where the application is a standard variation application for a homoeopathic product, £218;

(b) where the application is a new indication variation application, £350; and

(c) for any other application, £110.".

Amendment of Schedule 3 to the General Fees Regulations

4. In Schedule 3 to the General Fees Regulations (periodic fees for licences), in Part III (periodic fees for marketing authorizations and licences), in the table in paragraph 1—

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

"(g) National homoeopathic product"; and

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

"2(g) £63".

Amendment of the Homoeopathic Regulations

5. In Schedule 2 to the Homoeopathic Regulations (fees for applications for the grant of certificates of registration), in paragraph 3—

(a) after the definition of "formulation" insert—

""homoeopathic marketing authorization" means a marketing authorization granted by the licensing authority under the Marketing Authorisation Regulations(**11**) in respect of a national homoeopathic medicinal product;";

(b) after the definition of "mutual recognition procedure incoming application" insert—

""national homoeopathic product" has the meaning given by regulation 4(1B) of the Marketing Authorisation Regulations;";

(c) in the definition of "repeat formulation", in paragraph (a)—

(i) in sub-paragraph (i), after "certificate of registration" insert "or a homoeopathic marketing authorization",

(ii) in sub-paragraph (ii), after "certificate of registration" insert "or the homoeopathic marketing authorization"; and

(d) in the definition of "repeat stock", in paragraph (a)—

(i) in sub-paragraph (i), after "certificate of registration" insert "or a homoeopathic marketing authorization", and

(ii) in sub-paragraph (ii)—

(aa) after "a certificate of registration" insert "or a homoeopathic marketing authorization", and

(**11**) *See* the definition of "Marketing Authorisation Regulations" in section 132(1) of the Medicines Act 1968 (c. 67), as inserted by S.I. 2005/1094.

(bb) after "the certificate of registration" insert "or homoeopathic marketing authorization".

Signed by authority of the Secretary of State for Health

Andrew Burnham
Minister of State
20th July 2006 Department of Health

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

Andrew McCormick
Permanent Secretary
Department of Health, Social Services and
21st July 2006 Public Safety

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

Pat Toal
Permanent Secretary
Department of Agriculture and Rural
26th July 2006 Development

We consent,

Alan Campbell
Dave Watts
Two of the Lords Commissioners of Her
24th July 2006 Majesty's Treasury

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 principal Regulations") and the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 ("the Homoeopathic Regulations").

The principal 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 4 amend the principal Regulations so as to provide for the capital fees payable in connection with an application for the grant or variation of a marketing authorization for a "national homoeopathic medicinal product", and the periodic fee payable in connection with the holding of such an authorization. A national homoeopathic product is homoeopathic medicinal product which is not eligible for the procedure for registration under the Homoeopathic Regulations and is indicated only for the treatment of minor symptoms or conditions.

The Homoeopathic Regulations implemented in part Council Directive 92/73/EEC(**12**) (now repealed and re-enacted in Directive 2001/83/EC(**13**)) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for human use. The Homoeopathic Regulations also make provision for capital fees payable for applications for the grant and variation of certificates of registration. Regulation 5 amends Schedule 2 to the Regulations (fees for application for the grant of certificates of inspection) so that reduced fees are payable in respect of applications for certificates of registration in respect of products that have an identical formulation to, or are prepared from a homoeopathic stock identical to another homoeopathic stock used in the preparation of, a national homoeopathic product in respect of which a marketing authorization has been granted.

A full Regulatory Impact Assessment of the effect that this instrument will have on the costs of business 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.

(**12**) OJNo. L 297, 13.10.1992, p.8.
(**13**) *See* articles 1(5), 13 to 16, 53, 68, 69, 85, 100, 119 and 124.