STATUTORY INSTRUMENTS

2005 No. 1124

FEES AND CHARGES

MEDICINES

The Medicines for Human Use (Fees Amendments) Regulations 2005

Made - - - -	*6th April 2005*
Laid before Parliament	*7th April 2005*
Coming into force	
Except for the purposes of regulations 3 (2) and 4	*1st May 2005*
For the purposes of regulations 3 (2) and 4	*1st July 2005*

The Secretary of State, being a Minister designated for the purposes of section 2(2) of the European Communities Act 1972(**a**) in relation to medicinal products(**b**), in exercise of the powers conferred upon him by the said section 2(2), the Secretary of State, with the consent of the Treasury, in exercise of the powers conferred upon him by section 56(1) and (2) of the Finance Act 1973(**c**), the Secretary of State, the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, acting jointly and with the consent of the Treasury, in exercise of powers conferred upon them by section 1(1) and (2) of the Medicines Act 1971(**d**), or, as the case may be, powers conferred by those provisions and now vested in them(**e**), and in each case in exercise of all other powers respectively enabling them in that behalf, after consultation in accordance with section 129(6) of the Medicines Act 1968(**f**) with such organisations as appear to them to be representative of interests likely to be substantially affected, hereby make the following Regulations:

(**a**) 1972 c.68.
(**b**) S.I. 1972/1811.
(**c**) 1973 c.51.
(**d**) 1971 c.69; as amended by section 21 of the Health and Medicines Act 1988 (c.49). By virtue of section 1(3) of the 1971 Act, expressions used in that section have the same meaning as in the Medicines Act 1968 (c.67); *see* therefore section 1(1) of the 1968 Act, as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, by article 5 of, and the Schedule to, S.I. 1999/3142, and by article 5(1) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794, which contains a definition of "the Ministers" which is relevant to the powers being exercised in the making of these Regulations. *See also* regulation 9(12) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144), by virtue of which the references in section 1(1) and (2)(b) of the 1971 Act to a licence under Part II of the 1968 Act include reference to a marketing authorization under the 1994 Regulations.
(**e**) In the case of the Secretary of State, by virtue of article 2(1) of, and paragraph 1 of the Schedule to, S.I. 1999/3142 and article 3(1)(c) and (7) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794; and in the case of the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, by virtue of the powers vested in the Ministers in charge of those Departments by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47) which may now be exercised by the Departments by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c.1); the Departments were renamed by virtue of Article 3(4) and (6) of S.I. 1999/283 (N.I. 1).
(**f**) 1968 c.67; section 129(6) was extended by section 1(3)(b) of the Medicines Act 1971.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Fees Amendments) Regulations 2005 and shall come into force—

(a) except for the purposes of regulations 3(2) and 4, on 1st May 2005; and

(b) for the purposes of regulations 3(2) and 4, on 1st July 2005.

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

Amendment of regulation 13 of the General Fees Regulations

2. In regulation 13 of the General Fees Regulations (fees for inspections), at the end of paragraph (5) add ", if the time taken to make that inspection is not more than 2 hours".

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

3.—(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 column 2 of the Table in paragraph 1(1)—

(a) for "£25,690" substitute "£25,802";

(b) for "£56,106" substitute "£56,218";

(c) for "£80,586" substitute "£80,698";

(d) for "£15,577" substitute "£15,689";

(e) for "£22,254" substitute "£22,366";

(f) for "£5,708" substitute "£5,820";

(g) for "£8,160" substitute "£8,272";

(h) for "£2,225" substitute "£2,337"; and

(i) for "£1,483" substitute "£1,493".

(3) In paragraph 7(**b**) (clinical trial authorisations), head (iii) of paragraph (2)(b) is omitted.

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

4. In paragraph 2(a) of Part IIIA of Schedule 1 to the General Fees Regulations (capital fees for assessment of labels and leaflets), for "£319" substitute "£430".

Amendment of Schedule 5 to the General Fees Regulations

5. In Schedule 5 to the General Fees Regulations (waiver, reduction or refund of capital fees), after paragraph 2B(**c**), insert the following paragraph—

> **"2C.**—(1) Where an application for the grant of, or for a variation to, a marketing authorization, other than a major application, relates to a medicinal product which is intended to be used in accordance with an indication for use in the paediatric population, or a part of that population, and—
>
> (a) no product which contains the same active ingredient and is intended to be used in accordance with the same indication for use as the product in question has previously been granted a marketing authorization; or

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(**a**) 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, and 2004/666 and 1157.
(**b**) As amended by regulation 9(3)(b) of S.I. 2004/1157.
(**c**) Paragraph 2B was inserted by regulation 5(8) of S.I. 2002/542.

(b) a product which contains the same active ingredient and is intended to be used in accordance with the same indication for use as the product in question has previously been granted a marketing authorization, but is intended to be used for a different part of the paediatric population,

the fee payable under regulations 4 or 7(1)(a) in connection with that application may be waived.

(2) Where an application for the grant of, or for a variation to, a marketing authorization, other than a major application, relates to a medicinal product which is—

(a) intended to be used in accordance with an indication for use in the paediatric population, or a part of that population; and

(b) would, as a result of the application, be available in a formulation which the licensing authority considers to be of significant benefit to that population in comparison to other medicinal products on the market in the United Kingdom,

and no product which contains the same active ingredient and is in the same formulation as proposed for the product in question has previously been granted a marketing authorization, the fee payable under regulations 4 or 7(1)(a) in connection with that application may be waived.

(3) Where the licensing authority holds a meeting with a person for the purpose of providing scientific advice and that meeting was held with a view to that person making an application which falls within sub-paragraphs (1) or (2), the fee payable under regulation 3B may be waived.

(4) In this paragraph—

"active ingredient" has the same meaning as in Schedule 1;

"major application" has the same meaning as in Schedule 1;

"paediatric population" means that part of the population of the United Kingdom aged less than 18 years; and

"scientific advice" has the meaning given by regulation 3A.".

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
4th April 2005 Department of Health

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

D.C Gowdy
Permanent Secretary,
4th April 2005 Department of Health, Social Services and Public Safety

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

Pat Toal
Permanent Secretary,
31st March 2005 Department of Agriculture and Rural Development

We consent,

Jim Murphy and John Heppell
6th April 2005 Two of the Lords Commissioners of Her 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 General Fees Regulations").

The General Fees Regulations make provision for the fees payable under the Medicines Act 1971 relating to marketing authorizations, licences and certificates in respect of medicinal products for human use. Regulations 2 to 5 of these Regulations amend those Regulations as follows.

Regulation 2 amends regulation 13(5) of the General Fees Regulations so that the fee waiver for inspections made within six months of a previous inspection to check whether required improvements or alterations to the premises have been made will apply only when such an inspection does not last more than two hours.

Regulations 3(2) and 4 increase the level of capital fees payable from 1st July 2005 for certain categories of application for marketing authorizations and for one category of variation of such authorizations.

Regulation 3(3) amends the provision for fees for an application for a clinical trial authorisation so that the reduced fee for trials of medicinal products "known" to the licensing authority no longer applies to trials of products which do not have a marketing authorisation but for which a clinical trial has been authorised in another EEA State.

Regulation 5 makes provision for the waiver of fees payable in connection with applications for marketing authorizations, the variation of such authorizations, and pre-application meetings where these applications or meetings relate to medicinal products with indications for treatment of the paediatric population where the indications are new or for a new section of the paediatric population or the formulation is new and is of benefit to the paediatric population.

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