2003 No. 2321

FEES AND CHARGES

MEDICINES

The Medicines for Human Use (Fees and Miscellaneous Amendments) Regulations 2003

Made - - - - -	*8th September 2003*
Laid before Parliament	*9th September 2003*
Coming into force	
For the purposes of regulations 7(2)(a)(ii) & (b), (3) & (4)(a), 8(2)(b) & (3), 9, 11(2)(a), (b) & (c)(i), (ii), (iii)(aa) & (iv), (3), (4) & (6) and 13	*1st October 2003*
For all other purposes	*31st October 2003*

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

(**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).

them in that behalf, after consultation in accordance with section 129(6) of the Medicines Act 1968(**a**) with such organisations as appear to them to be representative of interests likely to be substantially affected, hereby make the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Fees and Miscellaneous Amendments) Regulations 2003.

(2) These Regulations shall come into force—

(a) for the purposes of—

(i) regulation 7(2)(a)(ii) and (b), (3) and (4)(a),

(ii) regulation 8(2)(b) & (3),

(iii) regulation 9,

(iv) regulation 11, except paragraphs (2)(c)(iii)(bb) and (5), and

(v) regulation 13,

on 1st October 2003, and

(b) for all other purposes, on 31st October 2003.

(3) In these Regulations, "the General Fees Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995(**b**).

Amendment of the Medicines Act 1968

2. In the Medicines Act 1968(**c**), in section 132 (interpretation), in paragraph (1), in the definition of "the 2001 Directive", after "human use" insert ", as amended(**d**)".

Amendment of the Standard Provisions Regulations 1971

3. In the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**e**)—

(a) in regulation 2 (interpretation), in paragraph (1), in the definition of "the 2001 Directive", after "human use" insert ", as amended"; and

(b) in Part I of Schedule 1 (standard provisions for product licences), in paragraph 16, for "Part 4G of Annex I to the 2001 Directive" substitute "point 6 of Part II of Annex I to the 2001 Directive".

Amendment of the Product Licences Regulations 1993

4. In the Medicines (Applications for Grant of Product Licences—Products for Human Use) Regulations 1993(**f**)—

(a) in regulation 1 (citation, commencement and interpretation), in paragraph (2), in the definition of "the 2001 Directive", after "human use" insert ", as amended"; and

(b) in Schedule 1 (information, documents etc. required in respect of applications)—

(i) in paragraph 17, for "Part 3, paragraph 1.1, second sub-paragraph of the Annex I to the 2001 Directive" substitute "paragraph (9) of the Introduction and general principles of Annex I to the 2001 Directive", and

(ii) in paragraph 18, for "Part 4, paragraph B.2 of the Annex I to the 2001 Directive" substitute "paragraph 5.2(a) of Part I of Annex I to the 2001 Directive".

(**a**) 1968 c. 67; section 129(6) was extended by section 1(3)(b) of the Medicines Act 1971.
(**b**) 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 and 2003/625.
(**c**) 1968 c. 67; relevant amendments were made by S.I. 2002/236.
(**d**) Directive 2001/83/EC was amended by Commission Directive 2003/63/EC (OJ No. L 159, 27.6.2003, p. 46).
(**e**) S.I. 1971/972; relevant amendments were made by S.I. 2002/236.
(**f**) S.I. 1993/2538; relevant amendments were made by S.I. 2002/236.

Amendment of the Homoeopathic Medicinal Products for Human Use Regulations 1994

5. In the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**a**), in regulation 1 (citation, commencement and interpretation), in paragraph (1), in the definition of "the 2001 Directive", after "human use" insert ", as amended".

Amendment of the Advertising Regulations 1994

6. In the Medicines (Advertising) Regulations 1994(**b**), in regulation 1 (citation, commencement and interpretation), in paragraph (1), in the definition of "the 2001 Directive", after "human use" insert ", as amended".

Amendment of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994

7.—(1) The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**c**) shall be amended as follows.

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

(a) in paragraph (2)—

(i) in the definition of "the 2001 Directive", after "human use" insert ", as amended", and

(ii) in the definition of "the relevant Community provisions"(**d**)—

(aa) omit "Regulation (EC) No. 541/95, as amended" and "Regulation (EC) No. 542/95, as amended", and

(bb) after "Regulation (EC) No. 847/2000" insert the following entries—

"Regulation (EC) No. 1084/2003(**e**), and

Regulation (EC) No. 1085/2003(**f**);"; and

(b) in paragraph (4), after sub-paragraph (b) insert the following sub-paragraph—

"(bb) any reference in these Regulations to an application for the variation of a marketing authorization includes a reference to a notification of such a variation, and any reference to an applicant for a variation to a marketing authorization includes a reference to a person submitting such a notification; and".

(3) After regulation 6 (revocation, suspension or variation of a United Kingdom marketing authorization or the suspension of the use or marketing of medicinal products), insert the following regulation—

"**Urgent safety restrictions**

6A.—(1) The licensing authority may, subject to and in accordance with the relevant Community provisions, impose an urgent safety restriction(**g**) on the holder of a United Kingdom marketing authorization.

(**a**) S.I. 1994/105; relevant amendments were made by S.I. 2002/236.
(**b**) S.I. 1994/1932; relevant amendments were made by S.I. 2002/236.
(**c**) S.I. 1994/3144; as amended by S.I. 1998/3105, 2000/292, 2001/795, 2002/236, 2002/542 and 2003/1618.
(**d**) The definition of "the relevant Community provisions" was substituted by regulation 8(a)(ii) of S.I. 2002/236.
(**e**) OJ No. L159, 27.6.2003, p.1.
(**f**) OJ No. L159, 27.6.2003, p.24.
(**g**) Expressions used in the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 have the same meaning as in the relevant Community provisions (by virtue of regulation 1(5)); for the definition of "urgent safety restriction" see article 3(5) of Regulation (EC) No. 1084/2003.

(2) Where the licensing authority imposes an urgent safety restriction in accordance with paragraph (1), the holder of the marketing authorization shall—

(a) implement the restriction within a period specified by the licensing authority; and

(b) apply to vary the authorization so as to take account of that safety restriction immediately and in any event not later than 15 days after the restriction was imposed.".

(4) In Schedule 3 (offences, penalties etc)(**a**)—

(a) after paragraph 3 insert the following paragraph—

"**3A.** Any person who is the holder of a marketing authorization who fails to implement an urgent safety restriction imposed on him by the licensing authority under regulation 6A or by the European Commission under Commission Regulation (EC) No. 1085/2003 shall be guilty of an offence."; and

(b) in paragraph 6, in sub-paragraph (c), for "paragraph D of Part 2 of Annex I to the 2001 Directive" substitute "paragraphs 3.2(9), 3.2.1.2(c) and 3.2.2.4(c) of Part I of Annex I to the 2001 Directive".

Amendment of regulation 2 of the General Fees Regulations

8.—(1) Regulation 2 of the General Fees Regulations (interpretation) is amended as follows.

(2) In paragraph (1)—

(a) in the definition of "the 2001 Directive", after "human use" insert ", as amended"; and

(b) in the definition of "variation" for "Article 2.1 of Commission Regulation (EC) No. 541/95" substitute "Article 3.1 of Commission Regulation (EC) No. 1084/2003".

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

"(3) In these Regulations any reference to an application for the variation of a marketing authorization includes a reference to a notification of such a variation, and any reference to an applicant for a variation to a marketing authorization includes a reference to a person submitting such a notification.".

Amendment of regulation 3B of the General Fees Regulations

9. In regulation 3B of the General Fees Regulations, after "an EC marketing authorization" insert "or an application for the variation of a marketing authorization".

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

10. In Part II of Schedule 1 of the General Fees Regulations (capital fees for applications for authorizations, licences and certificates), in paragraph 1, in sub-paragraph (1), in column 1 of the Table, in head (a) of entry 1, for "Section G of Part 4 of Annex I to the 2001 Directive" substitute "point 6 of Part II of Annex I to the 2001 Directive".

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

11.—(1) Part III of Schedule 1 of 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 "reclassification variation application"(**b**) insert the following definition—

(**a**) Schedule 3 was amended by S.I. 1998/3105, 2000/292 and 2002/236.

(**b**) The definition of "reclassification variation application" was inserted by regulation 5(6)(a)(i) of S.I. 2002/542.

""Extended Type II Complex Variation Application" means an application by a marketing authorization holder to vary a marketing authorization (not being a parallel import licence) so that the medicinal product is indicated for use—

(a) in a therapeutic area for which the product was not previously indicated for use, or

(b) in respect of an organ, or any other part, of the human body for which the product was not previously indicated for use, if the application is supported by data which comprises or includes the results of clinical trials or physico-chemical, microbiological or pharmacological and toxicological tests;";

(b) for the definitions of "Type I Application" and "Type II Application" substitute the following definitions—

""Type IA Application" means an application by a marketing authorization holder to vary a marketing authorization (not being a parallel import licence) which is a "minor variation" of Type IA within the meaning of Article 3.2 of Commission Regulation (EC) No. 1084/2003;

"Type IB Application" means an application by a marketing authorization holder to vary a marketing authorization (not being a parallel import licence) which is a "minor variation" of Type IB within the meaning of Article 3.2 of Commission Regulation (EC) No. 1084/2003;

"Type II Application" means an application by a marketing authorization holder to vary a marketing authorization (not being a parallel import licence) which is not—

(a) a reclassification variation,

(b) a Type IA Application,

(c) a Type IB Application,

(d) a Type II Complex Variation Application,

(e) an Extended Type II Complex Variation Application, or

(f) a change to which Annex II to Commission Regulation (EC) No. 1084/2003 applies;"; and

(c) in the definition of "Type II Complex Variation Application"(**a**)—

(i) after "variation of a marketing authorization" insert ", other than an Extended Type II Complex Variation Application,",

(ii) in paragraph (a), for "paragraph 3 (changes to strength, pharmaceutical form and route of administration) of Annex II to Commission Regulation (EC) No. 541/95" substitute "paragraph 2 (changes to strength, pharmaceutical form and route of administration) of Annex II to Commission Regulation (EC) No. 1084/2003",

(iii) in paragraph (b)—

(aa) for "article 3.1(b) of Commission Regulation (EC) No. 541/95" substitute "Article 3.3 of Commission Regulation (EC) No. 1084/2003", and

(bb) in sub-paragraph (ii), for "Section H of Part IV of Annex I to the 2001 Directive" substitute "paragraph 5.2.6 of Part I of Annex I to the 2001 Directive", and

(iv) in paragraph (c), in sub-paragraph (i), for the words from "the change is not a minor variation" to the end substitute "the change is not a variation which satisfies conditions 1, 3 and 4 specified in point 14 of Annex I to Commission Regulation (EC) No. 1084/2003 (change in the manufacturer of the active substance or starting material/reagent/intermediate in the manufacturing process of the active substance where no European Pharmacopoeia certificate of suitability is available)".

(**a**) The definition of "Type II Complex Variation Application" was amended by S.I. 1996/683, 1998/574 and 2002/236.

(3) In paragraph 2—

(a) for sub-paragraph (a) substitute the following sub-paragraphs—

"(a) where the application is a Type IA Application, £140;

(aa) where the application is a Type IB Application, £214;"; and

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

"(cc) where the application is an Extended Type II Complex Variation Application, £21,990;".

(4) In paragraph 3—

(a) for "Commission Regulation (EC) No. 541/95" substitute "Commission Regulation (EC) No. 1084/2003";

(b) for "Article 2.2" substitute "Article 3.4";

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

"(a) where the application is a Type IA Application, £220;

(aa) where the application is a Type IB Application, £334;"; and

(d) at the end of sub-paragraph (c) insert—

"; and

(d) where the application is an Extended Type II Complex Variation Application, £30,738.".

(5) In paragraphs 4 and 5, for "Section G of Part 4 of Annex I to the 2001 Directive", in both places those words appear, substitute "point 6 of Part II of Annex I to the 2001 Directive".

(6) In paragraph 14(**a**), after "Type II Complex Variation Application" insert "or Extended Type II Complex Variation Application".

Amendment of Schedule 3 to the General Fees Regulations

12. In Schedule 3 of the General Fees Regulations (periodic fees for licences), in Part I (interpretation), in paragraph 1, in the definition of "limited use drug", for "Section G of Part 4 of Annex I to the 2001 Directive" substitute "point 6 of Part II of Annex I to the 2001 Directive".

Amendment of Schedule 5 to the General Fees Regulations

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

(2) After paragraph 1, insert the following paragraph—

"**1A.**—(1) Where the licensing authority holds a meeting with a person for the purpose of providing scientific advice and that meeting was held—

(a) at the request of the authority; or

(b) with a view to that person making—

(i) an application for a marketing authorization which includes a reclassification element within the meaning of paragraph 1A of Part II of Schedule 1, or

(ii) a reclassification variation application within the meaning of paragraph 1 of Part III of Schedule 1,

the fee payable under regulation 3B may be waived.

(2) In this paragraph, "scientific advice" has the meaning given by regulation 3A.".

(**a**) Paragraph 14 was amended by regulation 4(4) of S.I. 1998/574.

(3) In paragraph 2, after "the licensing authority" insert "or in response to the imposition of an urgent safety restriction under regulation 6A of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994".

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
5th September 2003 Department of Health

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

D.C. Gowdy
Permanent Secretary,
5th September 2003 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,
5th September 2003 Department of Agriculture and Rural Development

We consent,

Nick Ainger
Joan Ryan
8th September 2003 Two of the Lords Commissioners of Her Majesty's Treasury

EXPLANATORY NOTE

(This note is not part of the Regulations)

These regulations make amendments to the Medicines Act 1968, the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1995 ("the Marketing Authorisations Regulations"), the Medicines (Products for Human Use—Fees) Regulations 1995 ("the General Fees Regulations") and various other statutory instruments relating to medicinal products.

The Marketing Authorisations Regulations implemented in part the following provisions of European Community law: Council Directives 65/65/EEC(**a**), 75/318/EEC(**b**), 75/319/EEC(**c**) and the Regulations adopted by the Commission under Article 15 of that Directive, 89/342/EEC(**d**), 89/343/EEC(**e**), 89/381/EEC(**f**), 92/26/EEC(**g**), 92/27/EEC(**h**) and 92/73/EEC(**i**), now repealed and re-enacted by Directive 2001/83/EC(**j**) ("the 2001 Directive"), and Council Regulation (EEC) No. 2309/93(**k**) and the Regulations adopted by the Commission under Article 15.4 or 22.1 of that Regulation. They provide for the manner of making applications for the grant, renewal or variation of a United Kingdom marketing authorization and for procedures for consideration, revocation, suspension and related matters. Regulation 7 of these Regulations amends the Marketing Authorisations Regulations as a consequence of—

(a) Commission Regulations (EC) No. 1084/2003(**l**) and No. 1085/2003(**m**), which make provision in relation to variations of marketing authorizations, including the adoption of urgent safety restrictions by competent authorities, and

(b) the adoption of Commission Directive 2003/63/EC(**n**), which amends the 2001 Directive by substituting a new Annex I setting out standards and protocols in respect of the testing of medicinal products for which applications for marketing authorization are made.

Regulations 2 to 6 amend the Medicines Act and various statutory instruments, so as to amend references to the 2001 Directive as a consequence of the adoption of Commission Directive 2003/63/EC.

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 and for certain other fees arising out of or relating to Community obligations in relation to such products. Regulations 8, 10 to 12 make changes to the provisions for fees for applications for marketing authorizations, and for variations of such authorizations, as a consequence of the adoption of Commission Regulation (EC) No. 1084/2003 and Commission Directive 2003/63/EC. In particular, regulation 11 makes provision for new fees for minor variations of Type IA and Type IB and for variations to add new indications for use of a product in a different therapeutic area or in respect of a different organ or other part of the human body ("Extended Type II Complex Variation Applications"). Regulation 9 amends regulation 3A of the General Fees Regulations so as to make provision for fees in respect of meetings at which the licensing authority provide scientific advice to potential applicants for variations to marketing authorizations. Regulation 13 amends Schedule 5 of the General Fees Regulations, which relates to refunds and waivers. Regulation 13(2) makes provision for the waiver of fees payable in connection with meetings at which the licensing authority provide scientific advice to potential applicants for marketing authorizations or variations of such authorizations. Regulation 13(3) provides for the waiver of fees for applications for variations of marketing authorizations which result from urgent safety restrictions imposed by the licensing authority.

(**a**) OJ No. L 22, 9.2.1965, p. 369.
(**b**) OJ No. L 147, 9.6.1975, p. 1.
(**c**) OJ No. L 147, 9.6.1975, p. 13
(**d**) OJ No. L 142, 25.5.1989, p. 14.
(**e**) OJ No. L 142, 25.5.1989, p. 16.
(**f**) OJ No. L 181, 28.6.1989, p. 44.
(**g**) OJ No. L 113, 30.4.1992, p. 5.
(**h**) OJ No. L 113, 30.4.1992, p. 8.
(**i**) OJ No. L 297, 13.10.1992, p. 8.
(**j**) OJ No. L 311, 28.11.2001, p. 67.
(**k**) OJ No. L 214, 24.8.1993, p. 1.
(**l**) OJ No. L 159, 27.6.2003, p. 1.
(**m**) OJ No. L 159, 27.6.2003, p. 24.
(**n**) OJ No. L 159, 27.6.2003, p. 46.

A Regulatory Impact Assessment in relation to these Regulations has been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines and Healthcare products Regulatory Agency, Room 16-107, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

STATUTORY INSTRUMENTS

2003 No. 2321

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ISBN 0-11-047502-X

9 780110 475028

£2.50

Printed and published in the UK by The Stationery Office Limited
under the authority and superintendence of Carol Tullo, Controller of
Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.
E1241 9/2003 131241 19585