
STATUTORY INSTRUMENTS

2002 No. 542

MEDICINES

FEES AND CHARGES

**The Medicines for Human Use and Medical Devices
(Fees and Miscellaneous Amendments) Regulations 2002**

<i>Made</i>	- - - -	<i>11th March 2002</i>
<i>Laid before Parliament</i>		<i>11th March 2002</i>
<i>Coming into force</i>	- -	<i>1st April 2002</i>

The Secretary of State, being a Minister designated for the purposes of section 2(2) of the European Communities Act 1972^{M1} in relation to medicinal products^{M2}, 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^{M3}, the Secretary of State concerned with health in England, the Minister of Agriculture, Fisheries and Food, the Minister of Health, Social Services and Public Safety and the Minister 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^{M4}, or, as the case may be, powers conferred by those provisions and now vested in them^{M5}, 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^{M6}, as extended by section 1(3)(b) of the Medicines Act 1971, with such organisations as appear to them to be representative of interests likely to be substantially affected, hereby make the following Regulations:—

Marginal Citations

- M1** [1972 c.68.](#)
- M2** [S.I. 1972/1811.](#)
- M3** [1973 c.51.](#)
- M4** [1971 c.69](#); as amended by section 21 of the [Health and Medicines Act 1988 \(c.49\)](#). By virtue of section 1(3) of the 1971 Act, expressions used in that section have the same meaning as in the [Medicines Act 1968 \(c.67\)](#), as amended by article 2(2) of, and Schedule 1 to, [S.I. 1969/388](#) and by article 5 of, and the Schedule to, [S.I. 1999/3142](#); see therefore section 1(1) of the 1968 Act, 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.

M5 In the case of the Secretary of State concerned with health in England, by virtue of articles 2(1) and 5 of, and the Schedule to, [S.I. 1999/3142](#); in the case of the Minister of Agriculture, Fisheries and Food, by virtue of articles 2(2) and 5 of, and the Schedule to, [S.I. 1999/3142](#); in the case of the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the [Northern Ireland Act 1998 \(c.47\)](#).

M6 [1968 c.67](#).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 2002 and shall come into force on 1st April 2002.

(2) In these Regulations—

“the Devices Regulations” means the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 ^{M7};

“the General Fees Regulations” means the Medicines (Products for Human Use—Fees) Regulations 1995 ^{M8};

“the Homoeopathic Products Regulations” means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 ^{M9}; and

“the Marketing Authorisations Regulations” means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 ^{M10}.

Marginal Citations

M7 [S.I. 1995/449](#); amended by [S.I. 1998/574](#), 1999/566, 2000/592 and 2001/795.

M8 [S.I. 1995/1116](#); amended by [S.I. 1996/683](#), 1998/574, 1999/566, 2000/592 and 3031, and 2001/795.

M9 [S.I. 1994/105](#); amended by [S.I. 1994/899](#), 1995/541, 1996/482, 1998/574, 1999/566, 2000/592 and 2001/795.

M10 [S.I. 1994/3144](#); amended by [S.I. 1998/3105](#), 2000/292, 2001/795 and 2002/236.

Amendment of the Homoeopathic Products Regulations

2.—(1) In regulation 6 of the Homoeopathic Products Regulations (grant of a certificate), omit paragraph (b).

(2) In regulation 9 of the Homoeopathic Products Regulations ^{M11} (suspension and revocation), omit paragraph (3).

(3) In regulation 14 of the Homoeopathic Products Regulations ^{M12} (fees for variations of certificates)—

(a) in paragraph (1)(a), for “£95” substitute “ £103 ”;

(b) in paragraph (1)(b)(i), for “£95” substitute “ £103 ”;

(c) in paragraph (1)(b)(ii), for “£45” substitute “ £51.50 ”;

(d) in paragraph (2)(a), for “£185” substitute “ £200 ”;

(e) in paragraph (2)(b)(i), for “£185” substitute “ £200 ”;

(f) in paragraph (2)(b)(ii), for “£185” substitute “ £200 ”;

(g) in paragraph (2)(b)(iii), for “£88” substitute “ £100 ”; and

(h) in paragraph (2)(b)(iv), for “£44” substitute “ £50 ”.

(4) In regulation 15(1) of the Homoeopathic Products Regulations ^{M13} (fees payable by holders of certificates), for “£12” substitute “ £13 ”.

(5) In the Table in Schedule 2 to the Homoeopathic Products Regulations ^{M14} (fees for applications for the grant of certificates of registration)—

(a) in column (2) (fees for applications in respect of products prepared from not more than 5 homoeopathic stocks)—

(i) for “£113” substitute “ £122 ”,

(ii) for “£341” substitute “ £368 ”, and

(iii) for “£562” substitute “ £607 ”; and

(b) in column (3) (fees for other applications)—

(i) for “£280” substitute “ £302 ”,

(ii) for “£502” substitute “ £542 ”, and

(iii) for “£736” substitute “ £795 ”.

Marginal Citations

M11 As amended by regulation 3 of [S.I. 1994/899](#).

M12 As amended by regulation 3(2) of [S.I. 2001/795](#).

M13 As amended by regulation 3(3) of [S.I. 2001/795](#).

M14 As amended by regulation 3(4) of [S.I. 2001/795](#).

Amendment of the Marketing Authorisations Regulations

3.—(1) The Marketing Authorisations Regulations are amended as follows.

(2) In regulation 5 (consideration, and grant or refusal, of an application for, or for renewal or variation of, a United Kingdom marketing authorization), omit paragraph (2).

(3) After regulation 5 (consideration, and grant or refusal, of an application for, or for renewal or variation of, a United Kingdom marketing authorization) insert the following regulation—

“ Classification of medicinal products

5A.—(1) Each marketing authorization granted by the licensing authority on or after 1st April 2002 shall be granted subject to a condition that the medicinal product to which the authorization relates is to be available—

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale.

(2) Where prior to 1st April 2002 a medicinal product is subject to a marketing authorization and that authorization contains a statement that it is to be available on one or more of the following bases—

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale,

it is a condition of the marketing authorization from 1st April 2002 that the product is to be available only on that basis or, as the case may be, those bases.”.

(4) In regulation 6 (revocation, suspension or variation of a United Kingdom marketing authorization or the suspension of the use or marketing of medicinal products), omit paragraph (8).

(5) Regulation 8 (control of sale or supply of relevant medicinal products) is hereby revoked.

(6) In paragraph 6(2) of Schedule 5 (labels), for head (a) substitute—

“(a) if the product would be subject to restrictions imposed under section 58 of the Act if it contained a higher proportion or level of any substance, except where the product is for external use only or contains any of the substances described in head (c) of this subparagraph, the words “Warning. Do not exceed the stated dose”.”.

Amendment of regulation 3 of the Devices Regulations

4. In regulation 3 of the Devices Regulations^{M15} (fees)—

- (a) in paragraph (1)(a), for “£3,029” substitute “ £3,271 ”;
- (b) in paragraph (1)(b), for “£6,726” substitute “ £7,264 ”;
- (c) in paragraph (2)(a), for “£599” substitute “ £647 ”;
- (d) in paragraph (2)(b), for “£1,676” substitute “ £1,810 ”;
- (e) in paragraph (3)(a), for “£2,285” substitute “ £3,271 ”;
- (f) in paragraph (3)(b), for “£6,406” substitute “ £7,264 ”;
- (g) in paragraph (4)(a), for “£570” substitute “ £647 ”;
- (h) in paragraph (4)(b), for “£1,596” substitute “ £1,810 ”;
- (i) in paragraph (5)(a), for “£30,972” substitute “ £33,450 ”; and
- (j) in paragraph (5)(b), for “£7,690” substitute “ £8,305 ”.

Marginal Citations

M15 As amended by regulation 4 of [S.I. 2001/795](#).

Amendment of the General Fees Regulations

^{F1}5.

F1 [Reg. 5](#) revoked (1.4.2008) by [The Medicines \(Products for Human Use-Fees\) Regulations 2008 \(S.I. 2008/552\)](#), [regs. 1, 48\(1\)](#), [Sch. 7](#) (with [reg. 48\(2\)](#))

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
Department of Health

Whitty
Parliamentary Under Secretary of State,
Department for Environment, Food and Rural
Affairs

Bairbre de Brún
Minister of Health, Social Services and Public
Safety

Brid Rodgers
Minister of Agriculture and Rural Development

We consent,

Anne McGuire
Nick Ainger
Two of the Lords Commissioners of Her
Majesty's Treasury

Changes to legislation: There are currently no known outstanding effects for the The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 2002. (See end of Document for details)

F²SCHEDULE

Regulation 5(9)

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

.....

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make further amendments to the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (“the Homoeopathic Products Regulations”), the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (“the Marketing Authorisations Regulations”), the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 (“the Devices Regulations”) and the Medicines (Products for Human Use-Fees) Regulations 1995 (“the General Fees Regulations”).

^{M16M17}The Homoeopathic Products Regulations implemented in part Council Directive [92/73/EEC](#) (now repealed and re-enacted in Directive [2001/83/EC](#)) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for human use. Regulation 2 of these Regulations amend the Homoeopathic Products Regulations. Regulation 2(1) and (2) amends regulations 6 and 9 of those Regulations to remove the requirement that decisions to grant, suspend and revoke a certificate of registration must be published in the Gazette. Regulation 2(3) increases the amounts of the fees payable for variations of certificates of registration, regulation 2(4) increases the fee payable by holders of certificates of registration and regulation 2(5) increases the amounts of the capital fees payable for applications for certificates of registration. These increases average overall 9.5%.

^{M18M19M20M21M22M23M24M25M26M27M28}The Marketing Authorisations Regulations implemented in part the following provisions of European Community law: Council Directives [65/65/EEC](#), [75/318/EEC](#), [75/319/EEC](#) and the Regulations adopted by the Commission under Article 15 of that Directive, [89/342/EEC](#), [89/343/EEC](#), [89/381/EEC](#), [92/26/EEC](#), [92/27/EEC](#) and [92/73/EEC](#), now repealed and re-enacted by Directive [2001/83/EC](#), and Council Regulation (EEC) No. 2309/93 and the Regulations adopted by the Commission under Articles 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 3 of these Regulations amends the Marketing Authorisations Regulations. Regulation 3(2) and (4) amends regulations 5 and 6 of those Regulations so as to remove the requirement that decisions to grant, revoke, suspend or vary a marketing authorization must be published in the Gazette. Regulation 3(3) inserts new regulation 5A into those Regulations (which relates to the provisions of Directive [92/26/EC](#), re-enacted as Title VI in Directive [2001/83/EC](#)), so as to provide that the classification of a medicinal product is a condition of the marketing authorization relating to that product, and regulation 3(5) and (6) makes consequential amendments.

^{M29}The Devices Regulations prescribe the fees which are payable where a notified body consults the competent body in accordance with Council Directive [93/42/EEC](#) concerning medical devices. Regulation 4 of these Regulations amends the Devices Regulations by increasing the amounts of the fees specified in regulation 3 of those Regulations by an average overall of 12.5%.

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. Regulation 5 of these Regulations amend those Regulations as follows. Regulation 5(3) and (7) inserts new Part IVA into the General Fees Regulations, and a new Part IV into Schedule 1 to those Regulations. These contain provisions relating to the setting of new capital fees in cases where the United Kingdom provides assistance to another EEA state arising out of an application for the renewal of a United Kingdom marketing authorization relating to a medicinal product that has been subject to certain procedures for the mutual recognition and harmonisation of marketing authorizations within the Community. Regulation 5(2) makes an amendment consequential on these provisions. Regulation 5(4) amends Part I of Schedule 1 to those Regulations so as to provide that where an application for the grant of a marketing authorization names a manufacturer of the active ingredient of the medicinal product in question different from the manufacturer of that ingredient in a product in respect of which a marketing authorization has previously been granted, the application is not a complex application if a European Pharmacopoeia certificate of suitability covering the active ingredient has been submitted with the application. Regulation 5(5) and (6) amends Parts II and III of Schedule 1 to those Regulations so as to provide that an additional fee is payable where an application for the grant of a marketing authorization, or for the variation of a marketing authorization, changes whether a medicinal product is available only on prescription, only from a pharmacy or on general sale, or provides that the basis on which it is to be made available is different from that of certain similar products. Regulation 5(8) makes an amendment so as to provide that the additional fee may be reduced in certain cases.

There is also a package of changes to the General Fees Regulations relating to the levels of capital fees payable for applications for marketing authorizations, manufacturers' licences, wholesale dealers' licences, clinical trial certificates and export certificates; capital fees payable for variations and renewals of such authorizations, licences and certificates; periodic fees payable in connection with the holding of certain authorizations and licences; and the fees payable in connection with site inspections (regulation 5(9) and the Schedule to these Regulations). Fees have been increased by approximately 8%.

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 Control Agency, Room 16-106, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

Changes to legislation:

There are currently no known outstanding effects for the The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 2002.