STATUTORY INSTRUMENTS

2001 No. 795

MEDICINES
FEES AND CHARGES

The Medicines for Human Use and Medical Devices (Fees and Miscellaneous Amendments) Regulations 2001

Made - - - -	*8th March 2001*
Laid before Parliament	*9th March 2001*
Coming into force - -	*1st April 2001*

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 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(**3**), 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(**4**), or, as the case may be, powers conferred by those provisions and now vested in them(**5**), 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(**6**), 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:—

(**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), 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 regultion 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 authorisation under the 1994 Regulations.
(**5**) 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).
(**6**) 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 2001 and shall come into force on 1st April 2001.

(2) In these Regulations—

"the Devices Regulations" means the Medical Devices (Consultation Requirements) (Fees) Regulations 1995(**7**);

"the General Fees Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995(**8**);

"the Homoeopathic Products Regulations" means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**9**);

"the Marketing Authorisations Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**10**).

Amendment of the Marketing Authorisations Regulations

2.—(1) In regulation 1(2) of the Marketing Authorisations Regulations (interpretation)—

(a) after the definition of "Community marketing authorisation" there shall be inserted the following definition—

> ""EEA State" means a contracting party to the Agreement on the European Economic Area signed at Oporto on 2nd May 1992(**11**) as adjusted by the Protocol signed at Brussels on 17th March 1993(**12**);";

(b) after the definition of "the EMEA" there shall be inserted the following definition—

> ""parallel import licence" means a United Kingdom marketing authorisation granted by the licensing authority under these Regulations in respect of a relevant medicinal product which is imported into the United Kingdom from another EEA state in accordance with the rules of Community law relating to parallel imports";

(c) the definition of "parallel import" shall be omitted; and

(d) for the definition of "United Kingdom marketing authorisation" there shall be substituted the following definition—

> ""United Kingdom marketing authorisation" means a marketing authorisation granted by the licensing authority under these Regulations and includes a parallel import licence.".

(2) In regulation 4(1) of the Marketing Authorisations Regulations (applications for the grant, renewal or variation of a United Kingdom marketing authorisation), for the words "any provision of Community law affecting" there shall be substituted the words "the rules of Community law relating to".

(3) In regulation 5 of the Marketing Authorisations Regulations (consideration, and grant or refusal, of an application for, or for renewal or variation of, a United Kingdom marketing authorisation)—

(**7**) S.I. 1995/449; amended by S.I. 1998/574, 1999/566 and 2000/592.
(**8**) S.I. 1995/1116; amended by S.I. 1996/683, 1998/574, 1999/566, 2000/592 and 2000/3031.
(**9**) S.I. 1994/105; amended by S.I. 1995/541, 1996/482, 1998/574, 1999/566 and 2000/592.
(**10**) S.I. 1994/3144; amended by S.I. 1998/3105 and 2000/292.
(**11**) OJ No. L1, 3.1.1994, p.3.
(**12**) OJ No. L1, 3.1.1994, p.572.

(a) in paragraph (1), after the word "provisions" at each place where it occurs, there shall be inserted the words "and (where applicable) the rules of Community law relating to parallel imports";

(b) in paragraph (2), after the words "every authorisation" there shall be inserted the words ", other than a parallel import licence,"; and

(c) in paragraph (4), after the words "the 1965 Directive" there shall be inserted the words "or in relation to a parallel import licence".

Amendment of the Homoeopathic Products Regulations

3.—(1) In regulation 1(2) of the Homoeopathic Products Regulations(**13**) (interpretation), in the definition of "standard variation"—

(a) at the end of paragraph (n) the word "or" shall be omitted;

(b) at the end of paragraph (o) there shall be inserted the word "or"; and

(c) after paragraph (o) there shall be inserted the following paragraph—

"(p) a change following modification to the manufacturing authorisation.".

(2) In regulation 14(**14**) of the Homoeopathic Products Regulations (fees for variations of certificates)—

(a) in paragraph (1)(a), for "£90" there shall be substituted "£95";

(b) in paragraph (1)(b)(i), for "£90" there shall be substituted "£95";

(c) in paragraph (2)(a), for "£176" there shall be substituted "£185";

(d) in paragraph (2)(b)(i), for "£176" there shall be substituted "£185"; and

(e) in paragraph (2)(b)(ii), for "£176" there shall be substituted "£185".

(3) In regulation 15(1)(**15**) of the Homoeopathic Products Regulations (fees payable by holders of certificates), for "£11" there shall be substituted "£12".

(4) In the Table in Schedule 2 to the Homoeopathic Products Regulations(**16**) (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 "£108" there shall be substituted "£113",

(ii) for "£325" there shall be substituted "£341", and

(iii) for "£535" there shall be substituted "£562"; and

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

(i) for "£267" there shall be substituted "£280",

(ii) for "£478" there shall be substituted "£502", and

(iii) for "£701" there shall be substituted "£736".

Amendment of regulation 3 of the Devices Regulations

4. In regulation 3 of the Devices Regulations(**17**) (fees)—

(**13**) As amended by S.I. 1998/574.
(**14**) As amended by regulation 2(1) of S.I. 2000/592.
(**15**) As amended by regulation 2(2) of S.I. 2000/592.
(**16**) As amended by regulation 2(3) of S.I. 2000/592.
(**17**) As amended by regulation 3 of S.I. 2000/592.

(a) in paragraph (1)(a), for "£2,885" there shall be substituted "£3,029";
(b) in paragraph (1)(b), for "£6,406" there shall be substituted "£6,726";
(c) in paragraph (2)(a), for "£570" there shall be substituted "£599";
(d) in paragraph (2)(b), for "£1,596" there shall be substituted "£1,676";
(e) in paragraph (5)(a), for "£29,326" there shall be substituted "£30,972"; and
(f) in paragraph (5)(b), for "£7,324" there shall be substituted "£7,690".

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

Hayman
Minister of State, Ministry of Agriculture,
Fisheries and Food

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

Bríd Rodgers
Minister of Agriculture and Rural Development

We consent,

Greg Pope
Jim Dowd
Two of the Lords Commissioners of Her Majesty's Treasury

[F2]SCHEDULE

Regulation 5(14)

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 Medical Devices (Consultation Requirements) (Fees) Regulations 1995 ("the Devices Regulations"), the Medicines (Products for Human Use—Fees) Regulations 1995 ("the General Fees Regulations"), the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 ("the Homoeopathic Products Regulations") and the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 ("the Marketing Authorisations Regulations").

The Marketing Authorisations Regulations implemented in part the following provisions of the European Community: Council Directives 65/65/EEC(**18**), 75/318/EEC(**19**), 75/319/EEC(**20**) and any Regulation adopted by the Commission under Article 15 of that Directive, 89/342/EEC(**21**), 89/343/EEC(**22**), 89/381/EEC(**23**), 92/26/EEC(**24**), 92/27/EEC(**25**), 92/73/EEC(**26**), Regulation (EEC) No. 2309/93(**27**) and any 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 authorisation and for procedures for consideration, revocation, suspension and related matters. Regulation 2 of these Regulations amends the Marketing Authorisations Regulations by inserting into regulation 1(2) of those Regulations a definition of "EEA State", omitting the definition of "parallel import", inserting a definition of "parallel import licence" and substituting a new definition of "United Kingdom marketing authorisation". Regulations 2(2) and (3) make amendments consequential on those new definitions. These amendments together with the amendments to the Fees Regulations referred to below clarify the status of the parallel import scheme.

The Homoeopathic Products Regulations implemented in part Council Directive 92/73/EEC(**28**) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for human use. These Regulations amend the Homoeopathic Products Regulations in the following way. Regulation 3(1) of these Regulations adds to the definition of "standard variation", regulation 3(2) increases the amounts of the fees payable for variations of certificates of registration,

(**18**) OJ No. L22, 9.2.1965, p.369.
(**19**) OJ No. L147, 9.6.1975, p.1.
(**20**) OJ No. L147, 9.6.1975, p.13.
(**21**) OJ No. L142, 25.5.1989, p.14.
(**22**) OJ No. L142, 25.5.1989, p.16.
(**23**) OJ No. L181, 28.6.1989, p.44.
(**24**) OJ No. L113, 30.4.1992, p.5.
(**25**) OJ No. L113, 30.4.1992, p.8.
(**26**) OJ No. L297, 13.10.1992, p.8.
(**27**) OJ No. L214, 24.8.1993, p.1.
(**28**) OJ No. L297, 13.10.1993, p.8.

regulation 3(3) increases the fee payable by holders of certificates of registration and regulation 3(4) increases the amounts of the capital fees payable for applications for certificates of registration. These increases average overall 5%.

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(**29**) concerning medical devices. Regulation 4 of these Regulations amends the Devices Regulations by increasing the amounts of certain of the fees specified in regulation 3 of those Regulations by an average overall of 5%.

The General Fees Regulations make provision for the fees payable under the Medicines Act 1971 relating to marketing authorisations, licences and certificates in respect of medicinal products for human use. These Regualtions amend those Regulations as follows: regulation 5(1) of these Regulations amends regulation 2(1) of those Regulations by inserting a definition of "parallel import licence" and amends the definition of "authorised medicinal product" to take account of this; regulation 5(6), (8), (9), (10) and (13) make amendments consequential on this; these amendments together with those made to the Marketing Authorisations Regulations referred to above clarify the status of the parallel import scheme. Regulation 5(2) renumbers regulations 4A–4C of the General Fees Regulations and regulations 5(4), (7) and (11) make amendments consequential upon this. Regulation 5(3) of these Regulations reduces the number of export certificates comprising a "set". Regulation 5(12) allows for the waiver of any fee payable in connection with a variation application for the purpose of demonstrating compliance with the "Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products", published by the European Commission.

There is also a package of changes to the General Fees Regulations relating to the levels of capital fees payable for applications for marketing authorisations, manufacturer's licences, wholesale dealer's licences, clinical trial certificates and export certificates; capital fees payable for variations and renewals of such authorisations, licences and certificates; periodic fees payable in connection with the holding of certain authorisations and licences; and the fees payable in connection with site inspections. Fees have been increased by approximately 5% except in the case of the fee for export certificates, which is increased by 30%.

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 16107, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

(**29**) OJ No. L169, 12.7.1993, p.1.

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 2001.