STATUTORY INSTRUMENTS

2000 No. 3031

MEDICINES

FEES AND CHARGES

The Medicines (Products for Human Use—Fees) Amendment Regulations 2000

Made - - - - -	*9th November 2000*
Laid before Parliament	*10th November 2000*
Coming into force - -	*1st December 2000*

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 by the said section 2(2) and of all other powers enabling him in that behalf, hereby makes the following Regulations:—

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Products for Human Use—Fees) Amendment Regulations 2000 and shall come into force on 1st December 2000.

(2) In these Regulations, "the principal Regulations" means the Medicines (Products for Human Use—Fees) Regulations 1995(**c**).

Amendment of regulation 2(1) of the principal Regulations

2. In regulation 2(1) of the principal Regulations (interpretation), after the definition of "Community marketing authorization" there shall be inserted the following definitions—

""concerned member State" means an EEA State, the competent authorities of which receive an application to obtain recognition, according to the procedure laid down in Chapter III of Directive 75/319/EEC, of a United Kingdom marketing authorization;

"Directive 75/319/EEC" means Council Directive 75/319/EEC(**d**) on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products;

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

(**a**) 1972 c. 68.
(**b**) S.I. 1972/1811.
(**c**) S.I. 1995/1116; amended by S.I. 1996/683, 1998/574, 1999/566 and 2000/592.
(**d**) OJ No. L 147, 9.6.175, p.13, This Directive has been amended by Council Directive 83/570/EEC (OJ No. L 332, 28.11.1983, p.1), Council Directive 89/342/EEC (OJ No. L 142, 25.5.1989, p.14), Council Directive 89/343/EEC (OJ No. L 142, 25.5.1989, p.16), Council Directive 89/381/EEC (OJ No. L 181, 28.6.1989, p.44), Council Directive 92/27/EEC (OJ No. L 113, 30.4.1992, p.8) and Council Directive 93/39/EEC (OJ No. L 214, 24.8.93, p.22).
(**e**) OJ No. L1, 3.1.1994, p.3.
(**f**) OJ No. L1, 3.1.1994, p.572.

New Part IIA of the principal Regulations

3. After Part II of the principal Regulations (capital fees for applications for authorizations, licences or certificates and for associated inspections) there shall be inserted the following Part—

"PART IIA

CAPITAL FEES FOR ASSISTANCE IN OBTAINING MARKETING AUTHORIZATIONS IN OTHER EEA STATES

Meaning of "set of applications"

4A. For the purposes of this Part and Part IIA of Schedule 1, a "set of applications" means—

(a) a number of applications to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Chapter III of Directive 75/319/EEC of a single United Kingdom marketing authorization in other EEA States, where those applications to the licensing authority all relate to applications for marketing authorizations in other EEA States that have the same 90 day assessment period for the purposes of article 9.4 of Council Directive 75/319/EEC; or

(b) a number of applications to competent authorities of other EEA States for marketing authorizations relating to a single United Kingdom marketing authorization, where those applications all have the same 90 day assessment period for the purposes of article 9.4 of Council Directive 75/319/EEC.

Applications for regulatory assistance under the mutual recognition procedure

4B. Subject to regulation 19, in connection with each application or set of applications to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Chapter III of Directive 75/319/EEC of a single United Kingdom marketing authorization in another EEA State or in other EEA States, there shall be payable by the applicant the fee prescribed in Part IIA of Schedule 1 in connection with that application or set of applications.

Time for payment of fees under regulation 4B

4C. Subject to regulations 17 and 19, all sums payable by way of fees under regulation 4B shall be payable at the time when, in connection with the application or set of applications for regulatory assistance, a request is made pursuant to the second sub-paragraph of article 9.3 of Directive 75/319 for an assessment report to be prepared or updated.".

Amendment of regulation 16 of the principal Regulations

4. In regulation 16 of the principal Regulations (time for capital fees in connection with applications or inspections), before the words "subject to" there shall be inserted the words "Except where regulation 4C applies and".

Amendment of Schedule 1 of the principal Regulations

5. After Part II of Schedule 1 to the principal Regulations (capital fees for authorizations, licences and certificates) there shall be inserted the following Part—

"PART IIA

CAPITAL FEES FOR ASSISTANCE IN OBTAINING MARKETING AUTHORIZATIONS IN OTHER EEA STATES

Interpretation

1. In this Part, a reference to—

(a) an application to the licensing authority for regulatory assistance means a reference to—

(i) a single application of that type, or

(ii) a set of applications of that type,

relating to a single United Kingdom marketing authorization; and

(b) an application for a marketing authorization in a concerned member State means a reference to—

(i) a single application of that type, or

(ii) a set of applications of that type in a number of concerned member States,

relating to a single United Kingdom marketing authorization.

Outgoing mutual recognition applications

2. The fee payable under regulation 4B in connection with an application to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Chapter III of Directive 75/319/EEC of a single United Kingdom marketing authorization in a concerned member State shall be—

(a) if the application in the concerned member State, had it been in the United Kingdom, would have been a major application—

(i) in respect of the first application for regulatory assistance to the licensing authority, a fee of £30,000, and

(ii) in respect of each other application for regulatory assistance to the licensing authority, a fee of £20,000;

(b) if the application in the concerned member State, had it been in the United Kingdom, would have been a complex application—

(i) in respect of the first application for regulatory assistance to the licensing authority, a fee of £7,500, and

(ii) in respect of each other application for regulatory assistance to the licensing authority, a fee of £5,000;

(c) if the application in the concerned member State, had it been in the United Kingdom, would have been a standard application—

(i) in respect of the first application for regulatory assistance to the licensing authority, a fee of £3,000, and

(ii) in respect of each other application for regulatory assistance to the licensing authority, a fee of £2,500; and

(d) if the application in the concerned member State, had it been in the United Kingdom, would have been a simple application, in respect of each application for regulatory assistance to the licensing authority, a fee of £1,795.".

Amendment of Schedule 4 to the principal Regulations

6.—(1) In Schedule 4 to the principal Regulations (time for payment of capital fees—applications by small companies), after paragraph 4 there shall be inserted the following paragraph—

"4A. As regards the fee payable under regulation 4B in connection with an application—

(a) to which paragraph 2(a) of Part IIA of Schedule 1 applies—

(i) 25% of that fee shall be payable at the time when, in connection with the application or set of applications for regulatory assistance, a request is made pursuant to the second sub-paragraph of article 9.3 of Directive 75/319 for an assessment report to be prepared or updated, and

(ii) 75% of that fee shall become payable within 30 days following written notice from the licensing authority that the regulatory assistance is at an end;

(b) to which paragraph 2(b), (c) or (d), of Part IIA of Schedule 1 applies—

(i) 50% of that fee shall be payable at the time when, in connection with the application or set of applications for regulatory assistance, a request is made pursuant to the second sub-paragraph of article 9.3 of Directive 75/319 for an assessment report to be prepared or updated, and

(ii) 50% of that fee shall become payable within 30 days following written notice from the licensing authority that the regulatory assistance is at an end,

if the applicant so requests in writing.".

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under-Secretary of State,
Department of Health

9th November 2000

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"). The principal Regulations make provision for the fees payable relating to marketing authorizations, licences and certificates in respect of medicines for human use.

Regulation 2 inserts new definitions into the principal Regulations that are relevant to the other new provisions being inserted. Regulation 3 inserts a new Part IIA into the principal Regulations. This contains provisions relating to the setting of new capital fees for assistance in obtaining marketing authorizations in other countries that are contracting parties to the Agreement on the European Economic Area ("EEA States"). The fees relate to a procedure laid down in Chapter III of Council Directive 75/319/EEC whereby companies that have obtained a marketing authorization in one EEA State can apply to have the authorization recognised in other EEA states, with assistance from the country that granted the original authorization.

Regulation 3 makes a consequential amendment to a provision in the principal regulations relating to the time at which capital fees under the Regulations are to be paid. Regulation 4 inserts a new Part IIA into Schedule 1 of the principal Regulations, which sets out the different amounts for the new fees. Regulation 5 contains a provision relating to the times at which small companies have to pay the new fees, allowing them to delay payment of part of the fee in prescribed circumstances.

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

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