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(Acts whose publication is obligatory)

COUNCIL REGULATION (EC) No 2743/98

of 14 December 1998

amending Regulation (EC) No 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products [1] (hereinafter referred to as the 'Agency'), and in particular Article 10 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament [2],

Whereas under Article 57(1) of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [3], the revenues of the Agency consist of a contribution and the fees paid by undertakings for obtaining and maintaining a Community marketing authorisation and for other services provided by the Agency;

Whereas the amounts and structure of the fees established by Regulation (EC) No 297/95 must be reviewed by 31 December 1997;

Whereas, in view of the experience gained since 1995, it is appropriate to maintain the general principles and overall structure of the fees as well as the main operational and procedural provisions established by the abovementioned Regulation;

Whereas for certain fees, however, the services to which they relate should be specified so as to facilitate their collection and improve the transparency and practical implementation of this Regulation;

Whereas new fees must also be established to cover all the services now provided by the Agency;

Whereas an annual fee must be introduced to ensure coverage of the costs connected with the supervision of authorised medicinal products; whereas a given part of this fee will have to be allocated to the competent national authorities required under the terms of Regulation (EEC) No 2309/93 to supervise the market on behalf of the Community; whereas, moreover, the rules for distribution amongst those authorities will have to be adopted by the Agency's Management Board in accordance with the procedure laid down in this Regulation;

Whereas in certain exceptional cases and for imperative reasons of public or animal health it must be possible to reduce the abovementioned fees; whereas, therefore, without prejudice to more specific provisions of Community law, any decision to reduce fees will have to be taken by the Executive Director on the basis of a critical examination of the situation specific to each case after consultation of the competent scientific committee,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 297/95 is hereby amended as follows:

1. Article 1 shall be replaced by the following:

'*Article 1*

Scope

Fees for obtaining and maintaining a Community authorisation to market medicinal products for human and veterinary use and for other services supplied by the Agency shall be levied in accordance with this Regulation.

The amounts of these fees shall be laid down in ecus.'

[1] OJ L 35, 15. 2. 1995, p. 1.
[2] OJ C 328, 26. 10. 1998.
[3] OJ L 214, 24. 8. 1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24. 3. 1998, p. 7).

2. Articles 3 to 10 shall be replaced by the following:

'*Article 3*

Medicinal products for human use covered by the procedures laid down in Regulation (EEC) No 2309/93

1. *Authorisation to market a medicinal product*

(a) Full fee

The fee for an application for authorisation to market a medicinal product supported by a full dossier is ECU 200 000. This fee covers a single strength associated with one pharmaceutical form.

The fee shall be increased by ECU 20 000 for each additional strength and/or pharmaceutical form submitted at the same time as the initial application for authorisation. This increase covers one additional strength and/or pharmaceutical form.

The fee shall be increased by ECU 5 000 for each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

(b) Reduced fee

A reduced fee of ECU 100 000 shall apply to applications for authorisation to market a medicinal product for which a full dossier need not be presented, as provided for in Article 4 of the third paragraph of point 8(a)(i) and (iii) of Directive 65/65/EEC or when recourse is had to point 8(a)(ii) of the third paragraph of Article 4 of the same Directive. This fee covers a single strength associated with one pharmaceutical form.

The fee shall be increased by ECU 20 000 for each additional strength and/or pharmaceutical form submitted at the same time as the initial application for authorisation. This increase covers one additional strength and/or pharmaceutical form.

The fee shall be increased by ECU 5 000 for each additional presentation of the same strength and pharmaceutical form submitted at the same time as the initial application for authorisation.

(c) Extension fee

This is the fee for each extension of a marketing authorisation which has already been granted:

— where the extension is for a new strength, a new pharmaceutical form, a new indication or a new method of administration, the fee shall be ECU 50 000,

— where the extension is for a new presentation of a strength, a pharmaceutical form or of a method of administration which are already authorised, the fee shall be ECU 10 000.

2. *Variation*

(a) Type I variation fee

The fee for a variation of minor importance to a marketing authorisation according to the classification established by the Commission Regulation applicable to the matter shall be ECU 5 000.

In the event of the same variation being introduced, this fee shall cover all authorised strengths, pharmaceutical forms and presentations.

(b) Type II variation fee

The fee for a variation of major importance to a marketing authorisation according to the classification established by the Commission Regulation applicable to the matter shall be ECU 60 000. It may be halved for certain Type II variations which do not involve detailed scientific evaluation, a list of which shall be drawn up in accordance with the procedure laid down in Article 11(2).

In the event of the same variation being introduced, this fee shall cover all authorised strengths, pharmaceutical forms and presentations.

3. *Renewal fee*

The fee for examining information available at the time of the five-yearly renewal of an authorisation to market a medicinal product shall be ECU 10 000. It shall be charged for each strength associated with a pharmaceutical form.

4. *Inspection fee*

The flat-rate fee for any inspection within or outside the Community is ECU 15 000. For inspections outside the Community, travel expenses shall be charged extra on the basis of actual cost.

5. *Transfer fee*

The fee for a change in the holder of the marketing authorisations to which the transfer relates shall be ECU 5 000. This covers all authorised presentations of a given medicinal product.

6. *Annual fee*

The annual fee for each medicinal product which has been granted a marketing authorisation shall be ECU 60 000. This covers all authorised presentations of a given medicinal product.

Article 4

Medicinal products for human use covered by the procedures laid down in Directive 75/319/EEC (*)

Arbitration fee

A fee of ECU 10 000 shall be payable where the procedures laid down in Articles 10(2), 11, 12 and 15 of Directive 75/319/EEC are initiated.

The fee shall be increased by ECU 40 000 where the procedures laid down in Articles 11 and 12 of Directive 75/319/EEC are initiated at the instigation of the applicant for or holder of the marketing authorisation.

Article 5

Medicinal products for veterinary use covered by the procedures laid down in Regulation (EEC) No 2309/93

1. *Authorisation to market a medicinal product*

(a) Full fee

The fee for an application for authorisation to market a medicinal product supported by a full dossier shall be ECU 100 000. It covers a single strength associated with one pharmaceutical form.

The fee shall be increased by ECU 10 000 for each additional strength and/or pharmaceutical form submitted at the same time as the initial application for authorisation. This increase covers one additional strength and/or pharmaceutical form.

The fee shall be increased by ECU 5 000 for each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

In the case of vaccines, the full fee shall be reduced to ECU 50 000, with each additional strength and/or pharmaceutical form and/or presentation entailing an increase of ECU 5 000.

For the purposes of this point (a), the number of target species is irrelevant.

(b) Reduced fee

A reduced fee of ECU 50 000 shall apply to applications for authorisation to market a medicinal product for which a full dossier need not be presented, as provided for in point 10(a)(i) and (iii) of the third paragraph of Article 5 of Directive 81/851/EEC or when recourse is had to point (ii) of the third paragraph of Article 5 of the same Directive. This fee covers a single strength associated with one pharmaceutical form of the medicinal product.

The fee shall be increased by ECU 10 000 for each additional strength and/or pharmaceutical form submitted at the same time as the initial application for authorisation. This increase covers one additional strength and/or pharmaceutical form.

The fee shall be increased by ECU 5 000 for each additional presentation of the same strength and pharmaceutical form submitted at the same time as the initial application for authorisation.

In the case of vaccines, the fee shall be reduced to ECU 25 000, with each additional strength and/or pharmaceutical form and/or presentation entailing an increase of ECU 5 000.

For the purposes of this paragraph (b), the number of target species is irrelevant.

(c) Extension fee

This is the fee for each extension of a marketing authorisation which has already been granted:

— where the extension is for a new strength, a new pharmaceutical form, a new species, a new indication or a new method of administration, the fee shall be ECU 25 000,

— where the extension is for a new presentation of a strength, of a pharmaceutical form or of a method of administration which are already authorised, the fee shall be ECU 5 000,

— in the case of vaccines, where the extension is for a new strength, a new pharmaceutical form, a new presentation or a new method of administration, the fee shall be ECU 5 000.

2. *Variation*

(a) Type I variation fee

The fee for a variation of minor importance to a marketing authorisation according to the classification established by the Commission Regulation applicable to the matter shall be ECU 5 000. The same fee shall be charged in respect of vaccines.

In the event of the same variation being introduced, this fee shall cover all authorised strengths, pharmaceutical forms and presentations.

(b) Type II variation fee

The fee for a variation of major importance to a marketing authorisation according to the classification established by the Commission Regulation applicable to the matter shall be ECU 30 000. It may be halved for certain Type II variations which do not involve detailed scientific evaluation, a list of which shall be drawn up in accordance with the procedure laid down in Article 11(2).

In the case of vaccines, the fee shall be ECU 5 000.

In the event of the same variation being introduced, this fee shall cover all authorised strengths, pharmaceutical forms and presentations.

3. *Renewal fee*

The fee for examining information available at the time of the five-yearly renewal of an authorisation to market a medicinal product shall be ECU 5 000. It shall be charged for each strength associated with a pharmaceutical form.

4. *Inspection fee*

The flat-rate fee for any inspection within or outside the Community shall be ECU 15 000. For inspections outside the Community, travel expenses shall be charged extra on the basis of actual cost.

5. *Transfer fee*

The fee for a change in the holder of the marketing authorisations to which the transfer relates shall be ECU 5 000. This covers all authorised presentations of a given medicinal product.

6. *Annual fee*

The annual fee for each medicinal product which has been granted a marketing authorisation shall be ECU 20 000. This covers all authorised presentations of a given medicinal product.

Article 6

Medicinal products for veterinary use covered by the procedures laid down in Directive 81/851/EEC

Arbitration fee

An arbitration fee of ECU 10 000 shall be payable where the procedures laid down in Articles 18(2), 19, 20 and 23 of Directive 81/851/EEC are initiated.

The fee shall be increased by ECU 20 000 where the procedures laid down in Articles 19 and 20 of Directive 81/851/EEC are initiated at the instigation of the applicant for or holder of the marketing authorisation.

Article 7

Establishment of maximum residue limits (MRL) for veterinary medicinal products

1. *Fees for establishing MRL*

A full MRL fee of ECU 50 000 shall be charged for an application to set an initial MRL for a given substance.

An additional MRL fee of ECU 15 000 shall be payable for each application to amend or extend an existing MRL, or to cover new species.

MRL fees shall be deducted from the fee payable for an application for marketing authorisation or an application to extend a marketing authorisation for the medicinal product containing the substance for which an MRL has been set where such applications are submitted by the same applicant. However, this deduction may total no more than one half of the fee to which it applies.

2. *MRL fee*

A fee of ECU 15 000 shall be charged for any application to set an MRL with a view to clinical trials.

The fee shall be deducted from the amount of the full MRL fee laid down in point 1.

Article 8

Various fees

1. *Fee for scientific advice*

   This fee shall be charged where an application is made for scientific or technical advice concerning the research and development of a medicinal product with a view to the possible submission of an application for marketing authorisation or an application to extend a marketing authorisation.

   — For medicinal products for human use the maximum fee is set at ECU 60 000.

   — For medicinal products for veterinary use the maximum fee is set at ECU 30 000.

   The detailed procedures for applying this point shall be adopted in accordance with the procedure laid down in Article 11(2).

2. *Fees for administrative charges*

   Fees shall be payable for administrative charges when documents or certificates are issued outside the framework of services covered by another fee provided for in this Regulation or upon conclusion of the administrative validation of a dossier resulting in rejection of the application for which the dossier was submitted. The unit amount of such fees may not exceed ECU 5 000. In accordance with Article 11(2) of this Regulation, a classification shall be established and specified by the Management Board of the Agency.

Article 9

Possible fee reductions

Without prejudice to more specific provisions of Community law, in exceptional circumstances and for imperative reasons of public or animal health, fee reductions may be granted case by case by the Executive Director after consultation of the competent scientific committee. Any decision taken pursuant to this Article shall state the reasons on which it is based.

A total or partial exemption may be granted, in particular for medicinal products for treating rare diseases or diseases affecting minor species.

Article 10

Due date and belated payment

1. Fees shall be payable on the date of receipt of the relevant application unless specific provisions stipulate otherwise.

   The arbitration fee shall be payable within 30 days following referral to the Agency; the annual fee shall be payable within 30 days of the first and each subsequent anniversary of the notification of the marketing authorisation decision.

   The inspection fee shall be payable within 30 days of the date on which the inspection was carried out.

2. Where any fee payable under this Regulation remains unpaid at its due date, and without prejudice to the Agency's capacity to institute legal proceedings conferred on it by Article 59 of Regulation (EEC) No 2309/93, the Executive Director of the Agency may decide either not to provide the requested services or to suspend all the services and procedures under way until the whole of the relevant fee has been paid.

3. Fees shall be paid in ecus or in the national currency of one of the Member States according to the exchange rates in force, which are fixed daily by the Commission. However, monthly conversion rates based on the earlier rates may be fixed according to a calculation established by the Agency's Management Board.

Article 11

Implementing rules

1. On a proposal from the Executive Director and following a favourable opinion from the Commission, the Agency's Management Board shall fix the rules for repaying a part of the resources deriving from the annual fees to the competent national authorities involved in Community market supervision.

2. Without prejudice to the provisions of this Regulation or of Regulation (EEC) No 2309/93, the Agency's Management Board may, on a proposal from the Executive Director, specify any other provision proving necessary for the application of this Regulation.

3. In the event of disagreement as to the classification of an application in one of the fee categories laid down in this Regulation, the Executive Director shall give a ruling after consultation of the competent scientific committee.

Article 12

Amendment

Any amendment to this Regulation shall be adopted by the Council acting by a qualified majority after consulting the European Parliament, on a proposal from the Commission.

However, amendments to the amounts of the fees established by this Regulation shall be adopted in accordance with the procedure laid down in Article 73 of Regulation (EEC) No 2309/93.

Within three years of the entry into force of this Regulation, the Commission will present a report on its implementation, after consultation of the Agency's Management Board.

Future reviews of fees shall be based on a comprehensive evaluation of the Agency's costs, including expenditure relating to Member States' rapporteurs.

(*) OJ L 147, 9.6.1975, p. 13. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).'

3. The existing Article 11 shall become Article 13.

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 December 1998.

For the Council
The President
W. MOLTERER