REGULATION (EC) No 297/95

Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products

(OJ No L 35 of 15. 2. 1995, p. 1)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, in particular Article 235 thereof,

Having regard to the proposal from the Commission,

Whereas Article 58 of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products ([1]), hereinafter referred to as 'the Agency' requires the Council to establish the structure and the amount of fees referred to in Article 57 (1);

Whereas Article 57 (1) of the Regulation establishes that the revenues of the Agency shall consist of a contribution from the Community, and the fees paid by undertakings for obtaining and maintaining a Community marketing authorization and for other services provided by the Agency;

Whereas Articles 6 (3) and 28 (3) respectively of Regulation (EEC) No 2309/93 require that any application for authorization for a medicinal product or any application for a variation be accompanied by the fee payable to the Agency for the examination of the application;

Whereas the calculation of the amount of the fees charged by the Agency must be based on the principle of the service actually provided;

Whereas the amount of the fees laid down in this Regulation should not be a determining factor for the applicant for an authorization where there is a choice between a centralized procedure and a national procedure;

Whereas the basic fee should be defined as the fee charged for the initial application for an authorization for a medicinal product plus a fee for each different strength and/or pharmaceutical form; whereas, however, a ceiling should be established;

Whereas to the same end, an extension fee should be laid down for subsequent applications regarding a medicinal product which has already been authorized in order to take account of the additional work and expenditure where an applicant chooses to submit the applications gradually and subsequently;

([1]) OJ No L 214 of 24. 8. 1993, p. 1.

Whereas provision should be made for a reduced fee for applications which may be sustained by a less detailed dossier pursuant to point 8 of the second paragraph of Article 4 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products ([1]) and point 8 of the second paragraph of Article 5 of Council Directive 81/851/EEC of 28 September 1981 on approximation of the laws of the Member States relating analytical, pharmaco-toxicological and clinical standards protocols in respect of the testing of veterinary medicinal products ([2]) respectively and for applications concerning a medicinal product for use in non-food producing animals;

Whereas the examination of variations to the terms of existing authorizations not requiring full evaluation of the product's quality, safety and efficacy should be charged according to the complexity of the variations and the real workload linked to them, and therefore at a rate far lower than for a standard application;

Whereas the work involved in the mandatory five-yearly renewal of a Community marketing authorization justified the charging of a fee;

Whereas a fee should be laid down for arbitration services in the event of disagreement between Member States on applications for authorizations submitted under the decentralized procedure;

Whereas a fee should be levied on a flat-rate basis for any inspection made successively to a marketing authorization at the request or in the interest of its holder;

Whereas the market for a veterinary medicinal product differs from that of a medicinal product for human use and therefore justifies a general reduction of the fee; whereas it should furthermore be possible to take account of the particular situation linked to the marketing of certain veterinary medicinal products on an individual basis; whereas this aim can best be achieved by means of special provisions such as a clause for reductions and waivers;

Whereas, as regards the evaluation of applications to establish maximum residue limits (MRLs), it is up to the applicant to decide whether to apply separately for the establishment of MRLs or to do so together with his application for a Community marketing authorization in which case the fee incurred for the evaluation of the application for authorization should cover the one for the establishment of MRLs; whereas, however, if the applicant deliberately chooses to apply separately for the establishment of MRLs, the additional work and expenditure should be recouped by means of an isolated MRL fee;

Whereas all other fees for the evaluation of veterinary medicinal products should follow the principles described above;

Whereas provision should be made for waivers or reductions of the fees stated above under exceptional circumstances for essential public health or animal health reasons; whereas any decision upon those cases should be taken by the Director after hearing the competent committee and on the basis of general criteria laid down by the Agency's Management Board;

([1]) OJ No 22 of 9. 2. 1965, p. 369/65. Directive as last amended by Directive 93/39/EEC (OJ No L 214 of 24. 8. 1993, p. 22).

([2]) OJ No L 317 of 6. 11. 1981, p. 1. Directive as last amended by Directive 93/40/EEC (OJ No L 214 of 24. 8. 1993, p. 31).

Whereas a provisional period of three years should be laid down after which the experience gained will enable the financial needs of the Agency to be re-assessed; whereas for practical reasons provision should also be made for machinery to permit rates to be updated over shorter periods;

Whereas the Treaty does not provide the necessary powers for fixing fees at Community level, within the framework of a Community system; whereas it is therefore appropriate to have recourse to Article 235 of the Treaty,

HAS ADOPTED THIS REGULATION:

Article 1

Scope

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

2. Fees shall be laid down in ecus.

Article 2

The Agency shall indicate in its annual estimate intended for the establishment of the preliminary draft budget of the Commission the estimates concerning the fees for the following financial year, and this shall be done separately from the estimating of the overall expenditure and the possible contribution by the Community.

Article 3

Applications for authorization for medicinal products for human use under the centralized procedure

1. Full fee: ECU 140 000

This is the fee for an application for a Community authorization to market a medicinal product supported by a full dossier. It shall be increased by ECU 20 000 for each additional strength and/or pharmaceutical form of the same medicinal product submitted at the same time as the initial application for authorization. However, the total amount of this fee may not exceed ECU 200 000.

2. Reduced fee: ECU 70 000

This is the fee for an application for a Community authorization to market a medicinal product not required to be supported by a full dossier as provided for under the exceptions in point 8 of the second paragraph of Article 4 of Directive 65/65/EEC. It shall be increased by ECU 10 000 for each additional strength and/or pharmaceutical form of the same medicinal product submitted at the same time as the initial application for authorization. However, the total amount of this fee may not exceed ECU 100 000.

3. **Extension fee: ECU 40 000**

   This is the fee for each additional application for a Community authorization to market a medicinal product made for a strength and/or pharmaceutical form after an initial application for authorization has been submitted to the Agency.

4. **Type I variation fee: ECU 5 000**

   This is the fee for a variation of minor importance according to the classification established by the Commission Regulation applicable to the matter.

5. **Type II variation fee: ECU 40 000**

   This is the fee for a variation of major importance according to the classification established by the Commission Regulation applicable to the matter.

6. **Renewal fee: ECU 10 000**

   This is the fee for review of the available new information about the medicinal product at the time of the obligatory five-yearly renewal of a Community marketing authorization for that product granted for each strength and/or pharmaceutical form.

7. **Inspection fee: ECU 10 000**

   This is the flat-rate fee for any inspection within or outside the Community. For inspections outside the Community travel expenses will be charged extra on the basis of the actual cost.

8. **Transfer fee: ECU 5 000**

   This is the fee for a change in the holder of each marketing authorization to which the transfer relates.

Article 4

Settlement of disagreements on applications for authorizations for medicinal products for human use under the decentralized procedure

Arbitration fee: ECU 30 000

This is the flat-rate fee paid by the undertaking concerned to the Agency for arbitration of disagreements between Member States on the mutual recognition of a national marketing authorization of a type II variation to be made to an existing national authorization. This fee shall also be charged where the procedures provided for in Articles 11 and 12 of Directive 75/319/EEC ([1]), are initiated at the instigation of the person responsible for placing medicinal products on the market.

([1]) OJ No L 147 of 9. 6. 1975, p. 13. Directive as last amended by Directive 93/39/EEC (OJ No L 214 of 24. 8. 1993, p. 22).

Article 5

Applications for authorizations for veterinary medicinal products under the centralized procedure

1. Full fee: ECU 70 000

This is the fee for an application for a Community authorization to market a medicinal product for use in food producing animals supported by a full dossier. It shall be increased by ECU 10 000 for each additional strength and/or pharmaceutical form of the same medicinal product submitted at the same time as the initial application. However, the total amount of this fee may not exceed ECU 100 000.

In the case of vaccines, the full fee is ECU 40 000, each additional strength and/or pharmaceutical form entailing an increase of ECU 5 000.

2. Reduced fee: ECU 35 000

This is the fee for an application for a Community authorization to market a medicinal product not required to be supported by a full dossier as provided for under the exceptions in point 10 of the second paragraph of Article 5 of Directive 81/851/EEC or for an application concerning a medicinal product for use in non-food producing animals. It shall be increased by ECU 5 000 for each additional strength, and/or pharmaceutical form of the same medicinal product or for a different species, submitted at the same time as the initial application. However, the total amount of this fee may not exceed ECU 50 000.

In the case of vaccines, the reduced fee is ECU 20 000, each additional strength and/or pharmaceutical form entailing an increase of ECU 5 000.

3. Maximum residue limits (MRL) fee: ECU 40 000

This is the fee for an application for the first MRL to be established for a substance. The fee for each request for modification or extension of an existing MRL shall be ECU 10 000.

This fee shall be deducted from that charged for a marketing authorization for a medicinal product containing the substance where such authorization is applied for by the undertaking originating the establishment of the MRL.

4. Extension fee: ECU 20 000

This is the fee for each additional application for a Community authorization to market a medicinal product made for a strength and/or pharmaceutical form after an initial application for authorization has been submitted to the Agency.

Unless an additional application for a strength and/or pharmaceutical form is made at the same time, this fee shall also be paid for an additional application to market the product for use in one or more additional species.

In the case of vaccines the additional fee shall be ECU 10 000.

5. Type I Variation fee: ECU 5 000

This is the fee for a variation of minor importance according to the classification established by the Commission Regulation applicable to the matter.

6. **Type II Variation free: ECU 20 000**

This is the fee for a variation of major importance according to the classification established by the Commission Regulation applicable to the matter.

7. **Renewal fee: ECU 5 000**

This is the fee for review of any available new information about the medicinal product at the time of the obligatory five-year renewal of a Community marketing authorization for that product granted for each strength, pharmaceutical form and/or species provided that species has been the subject of an extension fee within the meaning of paragraph 4 of this Article.

8. **Inspection fee: ECU 10 000**

This is the flat-rate fee for any inspection within or outside the Community. For inspections outside the Community travel expenses will be charged extra on the basis of the actual cost.

9. **Transfer fee: ECU 5 000**

This is the fee for a change in the holder of each marketing authorization to which the transfer relates.

Article 6

Settlement of disagreements on applications for authorizations for veterinary medicinal products under the decentralized procedure

Arbitration fee: ECU 15 000

This is the flat-rate fee paid by the undertaking concerned to the Agency for arbitration of disagreements between Member States on the mutual recognition of a national marketing authorization or of a type II variation to be made to an existing national authorization. This fee shall also be charged where the procedures provided for in Articles 19 and 20 of Directive 81/851/EEC, as amended, are initiated at the instigation of the person responsible for placing medicinal products on the market.

Article 7

Waivers, fee reductions and settlement of disagreements

1. In exceptional circumstances, and for imperative reasons of public or animal health waivers and fee reductions may be granted case by case, by the Executive Director after consultation of the competent Committee, for medicinal products with a limited number of applications. Decisions to grant waivers or reductions shall state the reasons on which they are based.

The general criteria for granting waivers and reductions shall be determined by the Agency's Management Board.

2. A procedure similar to that described in the first subparagraph of paragraph 1 shall apply to any disagreement which may arise on the classification of an application under one of the above fee categories.

Article 8

Due date and belated payment

1. Fees for which no due date is specified in this Regulation of Regulation (EEC) No 2309/93 shall be due on the date of receipt of the relevant application.

2. Where any fee payable under this Regulation remains unpaid at its due date the Executive Director may decide either not to provide or to suspend the services requested until 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 shall be fixed daily by the Commission in accordance with Regulation (EEC) No 3180/78 ([1]). However, the Agency's Management Board may fix monthly conversion rates on the basis of earlier rates.

Article 9

Implementing rules

Without prejudice to the other provisions of this Regulation or of Regulation (EEC) No 2309/93, implementing rules adopted by the Agency's Management Board shall lay down the due date for fees to paid under Article 1, the methods of their payment, the consequences of belated payment or non-payment and any other measure needed to apply this Regulation.

Article 10

Within two years at the latest of the entry into force of this Regulation, the Commission shall submit a report on its implementation and, in the light of that experience, propose a definitive Regulation to the Council. The Council, acting by a qualified majority after consulting the European Parliament, shall adopt provisions on the amounts of the fees and the conditions governing them, to apply as from I January 1998. Should these provisions not be applicable on that date, the amounts of the fees and the conditions governing them under this Regulation shall continue to apply provisionally.

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

([1]) OJ No L 379 of 30. 12. 1978, p. 1. Regulation as last amended by Regulation (EEC) No 1971/89 (OJ No L 189 of 4. 7. 1989, p. 1).

Article 11

Entry into force and legal effect

This Regulation shall enter into force on the day following 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, 10 February 1995.

For the Council

The President

A. JUPPE