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

(OJ L 35, 15.2.1995, p. 1)

Amended by:

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►**M1**	Council Regulation (EC) No 2743/98 of 14 December 1998	L 345	3	19.12.1998
►**M2**	Commission Regulation (EC) No 494/2003 of 18 March 2003	L 73	6	19.3.2003

Corrected by:

►**C1** Corrigendum, OJ L 75, 4.4.1995, p. 29 (297/95)

NB: This consolidated version contains references to the European unit of account and/or the ecu, which from 1 January 1999 should be understood as references to the euro — Council Regulation (EEC) No 3308/80 (OJ L 345, 20.12.1980, p. 1) and Council Regulation (EC) No 1103/97 (OJ L 162, 19.6.1997, p. 1).

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COUNCIL REGULATION (EC) No 297/95

of 10 February 1995

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, in particular Article 235 thereof,

Having regard to the proposal from the Commission,

►C1 Having regard to the European Parliament [1] ◄,

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 [2], 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;

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 [3] 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

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(1) Opinion delivered on 19 January 1995 (not yet published in the Official Journal).

(2) OJ No L 214, 24. 8. 1993, p. 1.

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

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products ([1]) 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;

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:

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Article 1

Scope

Fees for obtaining and maintaining a Community authorisation to market medicinal products for human and veterinary use and for other

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

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services supplied by the Agency shall be levied in accordance with this Regulation.

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

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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.

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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 ►M2 EUR 232 000 ◄. This fee covers a single strength associated with one pharmaceutical form.

The fee shall be increased by ►M2 EUR 23 200 ◄ 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 ►M2 EUR 5 800 ◄ 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 ►M2 EUR 116 000 ◄ 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 ►M2 EUR 23 200 ◄ 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 ►M2 EUR 5 800 ◄ 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 ►M2 EUR 58 000 ◄,

— 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 ►M2 EUR 11 600 ◄.

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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 ►**M2** EUR 5 800 ◄.

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 ►**M2** EUR 69 600 ◄. 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 ►**M2** EUR 11 600 ◄. 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 ►**M2** EUR 17 400 ◄. 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 ►**M2** EUR 5 800 ◄. 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 ►**M2** EUR 75 600 ◄. 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 [1]

Arbitration fee

A fee of ►**M2** EUR 11 600 ◄ 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 ►**M2** EUR 46 400 ◄ 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.

[1] 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).

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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 ►**M2** EUR 116 000 ◄. It covers a single strength associated with one pharmaceutical form.

The fee shall be increased by ►**M2** EUR 11 600 ◄ 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 ►**M2** EUR 5 800 ◄ 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 ►**M2** EUR 58 000 ◄, with each additional strength and/or pharmaceutical form and/or presentation entailing an increase of ►**M2** EUR 5 800 ◄.

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

(b) Reduced fee

A reduced fee of ►**M2** EUR 58 000 ◄ 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 ►**M2** EUR 11 600 ◄ 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 ►**M2** EUR 5 800 ◄ 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 ►**M2** EUR 29 000 ◄, with each additional strength and/or pharmaceutical form and/or presentation entailing an increase of ►**M2** EUR 5 800 ◄.

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 ►**M2** EUR 29 000 ◄,

— 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 ►**M2** EUR 5 800 ◄,

— in the case of vaccines, where the extension is for a new strength, a new pharmaceutical form, a new presentation or

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a new method of administration, the fee shall be ►M2 EUR 5 800 ◄.

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 ►M2 EUR 5 800 ◄. 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 ►M2 EUR 34 800 ◄. 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 ►M2 EUR 5 800 ◄.

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 ►M2 EUR 5 800 ◄. 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 ►M2 EUR 17 400 ◄. 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 ►M2 EUR 5 800 ◄. 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 ►M2 EUR 25 200 ◄. 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 ►M2 EUR 11 600 ◄ 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 ►M2 EUR 23 200 ◄ 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.

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Article 7

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

1. *Fees for establishing MRL*

A full MRL fee of ►**M2** EUR 58 000 ◄ shall be charged for an application to set an initial MRL for a given substance.

An additional MRL fee of ►**M2** EUR 17 400 ◄ 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 ►**M2** EUR 17 400 ◄ 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 ►**M2** EUR 69 600 ◄.

— For medicinal products for veterinary use the maximum fee is set at ►**M2** EUR 34 800 ◄.

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 ►**M2** EUR 5 800 ◄. 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.

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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.

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Article ►M1 *13* ◄

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*.

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