COMMISSION OF THE EUROPEAN COMMUNITIES

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PROPOSAL FOR A COUNCIL REGULATION (EC) AMENDING COUNCIL REGULATION (EC) No 297/95 ON FEES PAYABLE TO THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS

(presented by the Commission)

Explanatory memorandum

Introduction:

Pursuant to Council Regulation (EEC) No 2309/93 of 22 July 1993[1] 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 ("the EMEA"), the Council establishes the structure and the amount of fees paid by undertakings for obtaining and maintaining a Community marketing authorisation and for other services provided for by the EMEA.

The current level and structure of fees payable by the pharmaceutical industry to the EMEA was set out in Council Regulation (EC) No 297/95[2] adopted on 10 February 1995. Article 10 of this Regulation provides that 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 1 January 1998.

It was acknowledged by Council in 1995 that the level of fees provisionally adopted was a temporary arrangement during the transition period (1995 to 1997). They were not intended to fully cover the costs associated with the EMEA. Fee revenue is complemented by a substantial contribution from the EU general budget, in particular to cover the start-up costs for the Agency. The structure of EMEA fees was deliberately kept simple and, in line with orientations from Council, this was also to be re-examined along with the fee levels in the light of experience.

In preparing this proposal the Commission has sought to ensure to maintain the dual aims of not placing an undue burden on applicants and not endangering the achievement of the EMEA's primary task of providing scientific advice of the highest possible quality in relation to the authorisation and supervision of medicinal products.

The level of fees proposed by the Commission are comparable to the levels put forward in its initial proposal for Council Regulation (EC) No 297/95 (see COM(94) 167 final, 27.05.94). These figures were later substantially reduced during the decision-taking procedure. Despite EU budgetary difficulties, it is expected that there will be a continuing need for a contribution from the Community, in particular to guarantee the independence of the EMEA with regard to the sector in which it operates. This independence will be further ensured by the introduction of an annual fee, which is of a global nature and will therefore balance revenue from fees for services received from individual companies.

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[1] OJ L 214, 24.08.1993, p.1
[2] OJ L 35, 15.02.1995, p.1

Experience with the implementation of Regulation (EC) No 297/95:

The EMEA was invited by the European Commission to make a contribution to the preparation of this report based on its experience of the implementation of the Regulation.

A survey was carried out by the EMEA[3] on the costs of national competent authorities and the EMEA Secretariat associated with the operation of the centralised procedure.

The basic findings endorsed by the EMEA Management Board are:

- The current fee level does not cover the real costs incurred by either the national competent authorities or the Agency and would therefore have to be increased
- The majority of EMEA revenue should derive from fees, with a certain proportion of revenue continuing to come from the EU budget; this would permit the EMEA to pursue EU policies of general interest
- The current fee structure should be revised to introduce an annual fee for the funding of post-authorisation maintenance activities. Given the resource implications of scientific advice, a specific fee for that service should also be introduced
- A range of fees, as opposed to fixed fees, might be introduced to take into account the complexity and workload related to certain types of applications

The results of the survey showed that the average cost for national competent authorities who had acted as rapporteur or co-rapporteur in the evaluation of centralised applications for medicines for human use was ECU 78 130.

The costs of the EMEA Secretariat were calculated at ECU 188 710 per application. Different alternative analytical accounting methods applied since the completion of the EMEA report have confirmed the magnitude of these costs.

It appeared that the evaluation costs of veterinary medicinal products are similar to those of medicines for human use on the basis of the actual workload required for the applications. The EMEA Management Board therefore called for a convergence of fee levels between both sectors for activities such as applications for marketing authorisations and arbitrations.

Presentation of the proposal:

The fee levels proposed by the Commission are designed to permit the EMEA to continue to meet the high scientific and organisational standards required by Council Regulation (EEC) No 2309/93.

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[3] EMEA report *Contribution to the preparation of a Commission proposal for a definitive Council Regulation on fees payable to the EMEA*, EMEA/MB/057/96.Public

As a general principle, fees for obtaining Community marketing authorisations in the centralised procedure should be comparable to the benefit derived from a single procedure and authorisation throughout the Community. It should therefore be more or less equivalent to but in no case substantially higher than the total of fees charged by the 15 Member States[4].

The basic full fee for the evaluation of an application for medicinal products for human use is proposed at ECU 200 000 - the same level as put forward by the Commission in its initial proposal for the current fee Regulation (COM(94) 167 final, 27.05.94).

This increase in fee level is clearly demonstrated and supported by the cost survey of the national competent authorities and the EMEA.

The Commission's proposal foresees three major new orientations.

Firstly, the experience of the EMEA has shown that certain variations of major importance ('type II variations') do not necessarily involve detailed scientific evaluation. It is therefore proposed that the possibility should be introduced to permit the EMEA Management Board, on a proposal of the Executive Director, to determine those cases in which the fee payable for a type II variation may be halved.

The second initiative is the introduction of an annual fee which is destined to meet the costs associated with the supervision and maintenance of medicinal products granted a Community marketing authorisation. These activities are an increasingly important part of the responsibilities of all regulatory authorities. They also draw heavily on the resources of competent authorities since they are carried out continuously throughout the life of a product.

The introduction of an annual fee as proposed by the Commission is in line with the practices of many national competent authorities. According to information submitted to the EMEA Secretariat, annual fees are in fact levied by national competent authorities in 11 of the 15 Member States (all Member States except Belgium, Germany, Austria and Italy). Levels of annual fees vary considerably between national authorities, from ECU 13 in Luxembourg to a sales-based fee potentially exceeding ECU 21 000 levied by the UK Veterinary Medicines Directorate. As the EMEA moves to increasing reliance on revenue from fees, annual fees will contribute to the stability of financial planning. A part of the annual fee will have to be redistributed to Member States to cover the costs of market supervision undertaken on behalf of the Community. The rules for distribution among Member States will have to be adopted by the Agency's Management Board.

Thirdly, the proposal also provides for the introduction of a fee for scientific advice and protocol assistance given to future applicants in the design of their research and development programmes. The experience of the EMEA has shown that this service can demand considerable scientific and resource input. From the perspective of future applicants, the provision of scientific advice on matters to which no alternative guidance is readily available can be of considerable advantage in reducing questions raised by the EMEA during evaluation of an application for marketing authorisations.

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[4] Account should also be taken of the fact that under the EEA-Treaty, the scope of application of a central marketing authorisation will possibly be extended to Norway, Iceland and - under specific circumstances - also to Liechtenstein.

New provisions also include initiatives for a fee for the establishment of maximum residue limits ('MRLs') for clinical trials, administrative charges and the introduction of differentiated fees for the initiation of Community referral procedures under Council Directives 75/319/EEC and 81/851/EEC.

In spite of the EMEA's finding that the evaluation costs of veterinary medicinal products are similar to those of medicines for human use it was decided to take account of the specificity of the market of veterinary medicinal products and the public and animal health issues involved and to maintain the reduced fees for veterinary medicinal products

In accordance with Article 58 of Regulation (EEC) No 2309/93, a draft of the present proposal was forwarded to organisations representing the interests of the pharmaceutical industry at Community level. The Commission carefully examined and considered all comments received before submitting the present proposal.

The evolution of fees from Council Regulation (EC) No 297/95 and the current proposal is shown in the following comparative table:

Fees for medicinal products for human use

	Council Regulation (EC) No 297/95	Commission proposal
Full fee	ECU 140 000 to 200 000 (add ECU 20 000 for additional strength and/or pharmaceutical forms)	ECU 200 000 (add ECU 20 000 for additional strength and/or pharmaceutical forms and ECU 5 000 for each additional presentation)
Reduced fee	ECU 70 000 to 100 000 (add ECU 10 000 for additional strength and/or pharmaceutical forms)	ECU 100 000 (add ECU 20 000 for additional strength and/or pharmaceutical forms and ECU 5 000 for each additional presentation)
Extension fee	ECU 40 000	ECU 50 000 for new strength, pharmaceutical form or indication ECU 10 000 for new presentation of a strength and form already authorised
Type I variation	ECU 5 000	ECU 5 000
Type II variation	ECU 40 000	ECU 60 000 (possible reduction by half for specific type II applications)
Five year renewal fee	ECU 10 000	ECU 10 000
Inspection fee	ECU 10 000	ECU 15 000
Transfer of MA holder fee	ECU 5 000	ECU 5 000
Arbitration fee	ECU 30 000	ECU 10 000 where referral made by national authorities or Commission ECU 50 000 where referral made by applicant or MA holder
Annual fee	n/a	ECU 60 000
Fee for scientific advice	n/a	ECU 60 000

Fees for medicinal products for veterinary use[5]

	Council Regulation (EC) No 297/95	Commission proposal
Full fee	ECU 70 000 to 100 000 (add ECU 10 000 for additional strength and/or pharmaceutical forms)	ECU 100 000 (add ECU 10 000 for additional strength and/or pharmaceutical forms and ECU 5 000 for each additional presentation)
Reduced fee	ECU 35 000 to 50 000 (add ECU 5 000 for additional strength and/or pharmaceutical forms)	ECU 50 000 (add ECU 10 000 for additional strength and/or pharmaceutical forms and ECU 5 000 for each additional presentation)
Extension fee	ECU 20 000	ECU 25 000 for new strength, pharmaceutical form or indication ECU 5 000 for new presentation of a strength and form already authorised
Type I variation	ECU 5 000	ECU 5 000
Type II variation	ECU 20 000	ECU 30 000 (possible reduction by half for specific type II applications)
Maximum residue limit (MRL) fee	ECU 40 000	ECU 50 000
Modification or extension of an existing MRL	ECU 10 000	ECU 10 000
MRL for clinical trials	n/a	ECU 15 000
Five year renewal fee	ECU 5 000	ECU 5 000
Inspection fee	ECU 10 000	ECU 15 000
Transfer of MA holder fee	ECU 5 000	ECU 5 000
Arbitration fee	ECU 15 000	ECU 10 000 where referral made by national authorities or Commission ECU 25 000 where referral made by applicant or MA holder
Annual fee	n/a	ECU 30 000
Fee for scientific advice	n/a	ECU 30 000

[5] The Commission proposal provides for a reduction by half for applications for marketing authorisations for veterinary vaccines (i.e. full fee of ECU 50 000), type II variations are subject to a fee of ECU 5 000.

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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,[2]

Whereas under Article 57(1) of Council Regulation 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 before 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 they relate to 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 go 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 among those authorities will have to be adopted by the Agency's Management Board in accordance with the procedure laid down in this Regulation;

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[1] OJ L 35, 15.02.95, p. 1.

[2]

[3] OJ L 214, 24.08.93, p. 1.

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 is replaced by the following text:

"Article 1

Scope

Fees for obtaining and maintaining a Community authorisation 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.

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

2. Articles 3 to 11 are replaced by the following text:

"Article 3

Medicinal products for human use covered by the procedures laid down in Council 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. It covers only one presentation of the medicinal product (for one 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 only one presentation of the 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 point 8(a)(i) and (iii) of Directive 65/65/EEC or when recourse is had to Article 4 point 8 (a)(ii) of the same Directive. This fee covers a single presentation (for one 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 only one presentation of the 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 or a new indication, the fee is ECU 50 000;

- where the extension is for a new presentation of a strength and a pharmaceutical form which are already authorised, the fee is 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 is ECU 5 000.

(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 is 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) of this Regulation.

(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 is 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 will 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 is ECU 5 000. This covers all presentations of a given medicinal product.

(6) Annual fee

The annual fee for each medicinal product which has been granted a marketing authorisation is 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 Council Directive 75/319/EEC.[4]

An arbitration 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 Council 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 100 000. It covers only one presentation of the medicinal product (for one 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 only one presentation of the additional strength and/or pharmaceutical form.

[4] OJ L 147, 9.6.1975, p. 13. Directive last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).

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 is 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 paragraph, 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 Article 5 point 10(a)(i) and (iii) of Directive 81/851/EEC or when recourse is had to Article 5 point 10 (a)(ii) of the same Directive. This fee covers a single presentation (for one 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 only one presentation of the 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 is 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, 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 or a new species, the fee is ECU 25 000;

- where the extension is for a new presentation of a strength and a pharmaceutical form which are already authorised, the fee is ECU 5 000;

- in the case of vaccines, where the extension is for a new strength, a new pharmaceutical form or a new presentation, the fee is 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 is ECU 5 000. The same fee is charged in respect of vaccines.

(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 is 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) of this Regulation.

In the case of vaccines, the fee is ECU 5 000.

(3) Renewal fee

The fee for examining available information at the time of the five-yearly renewal of an authorisation to market a medicinal product is 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 is ECU 15 000. For inspections outside the Community, travel expenses will 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 is ECU 5 000. This covers all presentations of a given medicinal product.

(6) Annual fee

The annual fee for each medicinal product which has been granted a marketing authorisation is ECU 30 000. This covers all authorised presentations of a given medicinal product.

Article 6

Medicinal products for veterinary use covered by the procedures laid down in Council Directive 81/851/EEC[5]

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.

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[5] OJ L 147, 9.6.1975, p. 13. Directive last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).

The fee shall be increased by ECU 15 000 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 10 000 shall be payable for each application to amend or extend an existing MRL, including to cover new species.

MRL fees will 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 a 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) 'Maximum residue limit for clinical trials' fee

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

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

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 a medicinal product before an application is submitted for authorisation to market it.

- For medicinal products for human use the fee is set at ECU 60 000.
- For medicinal products for veterinary use the fee is set at ECU 30 000.

(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.

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 in application of this Article shall state the reasons on which it is based.

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 following the anniversary of the notification of the marketing authorisation decision.

The inspection fee shall be payable at the latest within 30 days following 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 Council 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 shall be 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.

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

Article 2

Entry into force

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, ...

FINANCIAL STATEMENT

1. TITLE OF OPERATION

Proposal for a Council Regulation on fees payable to the European Agency for the Evaluation of Medicinal Products.

2. BUDGET HEADING INVOLVED

- European Community contribution B5-3 1 2 0

- EMEA own budget (see, e.g., EMEA statement of revenue and expenditure for financial year 1997, OJ No L.79 of 20 March 1997, page 31)

3. LEGAL BASIS

Articles 57 and 58 of Council Regulation (EEC) No 2309/93 of 22 July 1993.

The presentation of this second Regulation is provided for in Article 10 of Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products.

4. DESCRIPTION OF OPERATION

4.1 General objective

- Completion of the internal market in the pharmaceuticals sector (medicinal products for human and veterinary use).

- Contribute to protection and promotion of public and animal health and consumer protection through:

    - a European system for the centralised evaluation and authorisation of biotechnology-derived and other innovative medicinal products;
    - limiting risks of veterinary medicine residues in food-producing animals;
    - an arbitration mechanism where Member States are unable to agree on the mutual recognition of national marketing authorisations; and
    - a Europe-wide system for the surveillance of safety of medicines.

4.2 Specific objectives

Council Regulation (EEC) No 2309/93 of 22 July 1993 lays down (centralised) Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishes a European Agency for the Evaluation of Medicinal Products ("EMEA"). Three Council Directives (93/39/EEC, 93/40/EEC and 93/41/EEC) complete the system for the authorisation of medicinal products under the decentralised (mutual recognition) procedure.

Article 57(1) of Council Regulation 2309/93 provides that the resources of the EMEA shall consist of:

- a contribution from the Community, and
- fees paid by undertakings for obtaining and maintaining a Community marketing authorisation and for other services provided by the EMEA

Council Regulation (EC) No 297/95 was adopted to implement a structure and level of fees payable to the EMEA.

This proposal is presented in accordance with Article 10 of that Regulation under which Council, in consultation with Parliament, is required to adopt further provisions to apply as from 1 January 1998 on the basis of practical experience of the implementation of the Regulation.

4.3 Period covered and arrangements for renewal or extension

The proposed Regulation has no fixed duration.

The proposal provides that while Council determines the categories of fees levied on applicants, the actual level of fees may be modified by means of a Standing Committee procedure as set out in Article 73 of Council Regulation (EEC) No 2309/93.

Any other changes to the Regulation may only be made by Council after consultation of European Parliament.

Within five years of its entry into force, the Commission will present a report on the implementation of the Regulation.

5. CLASSIFICATION OF EXPENDITURE OR REVENUE

The contribution from the general budget of the European Community is classified as:

- Non-compulsory expenditure
- Differentiated appropriations

Revenue from fees and other administrative charges levied on applicants and holders of Community marketing authorisations are own resources for the EMEA budget.

6. TYPE OF EXPENDITURE OR REVENUE

6.1 Revenue of the EMEA

- Partial contribution to the revenue of the EMEA from the Community budget
- Income from fees generate own resources for the EMEA budget

The proportion of fees in the total EMEA budget is expected to rise to about 75 percent by the year 2000. Taking into account the increase in activities of the EMEA, the Community contribution should stabilise, at about the 1997 level of ECU 14 million.

6.2 Expenditure of the EMEA

- Staff costs:

  Title I of the budget covers salary costs of EMEA personnel, together with costs of interim and other external support staff. Other staff-related expenditure (social welfare, staff missions, annual medical costs, recruitment costs, etc.) is also made under this title.

- Building and equipment costs:

  Title II relates to expenditure for the building occupied by the EMEA, costs associated with the rental of the building, equipment, IT networks and other miscellaneous operational costs. The costs of external studies are also met from this title.

- Operational expenditure:

  Title III of the budget relates to the operational expenditure of the EMEA. This covers in particular the costs of meetings and payments made to Member State national competent authorities for the provision of rapporteur and inspection services.

7. FINANCIAL IMPACT

7.1 Method of calculating the total cost of the action

The cost of the action is calculated on the basis of workload projections prepared on the basis of consultation with appropriate industry representative organisations and directly with undertakings in the sector. The budgetary needs are therefore established in line with the operational resources required to meet this expected workload and the work programme of the EMEA.

EMEA budgetary perspectives (ECU millions)					
	1998	1999	2000	2001*	2002*
EMEA budgetary needs	33.9	44	48	52	56
Projected fee revenue	19.6	29.6	33.6	37.6	41.6
Miscellaneous revenue (bank, interest etc)	0.3	0.4	0.4	0.4	0.4
Shortfall to be met by Community contribution	14	14	14	14	14

Article 71 of Council Regulation (EEC) No 2309/93 provides that the Commission will produce a report for the year 2000 on the European authorisation system, including the operation of the EMEA. This may lead to a revision of the scope of the centralised procedure and activities of the EMEA.

It is therefore difficult to provide a meaningful forecast of activities over the next 5 year period beyond the year 2000. On the basis of the current scope of the activities of the EMEA the contribution of the Community is not likely to exceed present levels.

Projected fee revenue is calculated on the basis of fee levels and structure presented in this proposal using a model based on the practical experience of the EMEA.

Calculations only take into account the normal activities of the EMEA within the European Union. The extension of EMEA activities, e.g. to countries of the European Economic Area or the accession of new Member States, would require additional resources.

7.2 Itemised breakdown of cost

At the request of the Commission, a contribution to the preparation of the new Regulation was made by the EMEA which looked at the costs of Member States and EMEA Secretariat in the operation of the centralised procedure. The report surveyed Member State competent authorities on the actual costs associated with the evaluation of medicinal products for which

* These projections are made on the basis that EMEA scope of activities will not be changed

they had acted as rapporteur or co-rapporteur, or for which their inspection departments had provided services. The survey also looked at the costs of the EMEA Secretariat.

The report of the Board, included detailed analysis of:

- actual costs of rapporteur and co-rapporteurship relating to the centralised evaluation of individual human and veterinary medicines
- costs of inspections carried out under the centralised procedure
- costs for variations, post-marketing surveillance, etc.
- estimated EMEA secretariat costs
- breakdown of the expected resource contributions from the Member States to EMEA activities

The report was adopted by the Management Board of the EMEA on 5 February 1997 and transmitted to the Commission. The report, after deletion of confidential information, was also circulated to appropriate European interested parties and made available to the public (EMEA/MB/057/96.Public).

The Management Board made a number of findings, including:

- fee levels provided for in Council Regulation (EC) No 297/95 do not cover the real costs incurred by either the national competent authorities or the EMEA, and that therefore fee levels should be increased

- current fee structure should be revised to introduce an annual fee for the funding of post-authorisation surveillance and maintenance activities

- the Board also recommended that by the year 2000 the majority of EMEA revenue should derive from fees, with perhaps 25 percent of revenue continuing to come from the EU budget

- the analysis of actual costs incurred by national competent authorities revealed that the average cost of evaluation for a medicinal product for human use was almost ECU 80 000 - considerably higher than the ECU 35 000 to 50 000 currently payable to rapporteurs or co-rapporteurs

The Board also highlighted:

- that costs associated with evaluation-related services provided by the EMEA should be recovered from fees levied on applicants and Community marketing authorisation holders

- the importance of compensation paid to them to finance their involvement in EMEA activities

7.3 Provisional schedule of appropriations

Not applicable, since this is a Community contribution to the EMEA budget.

7.4 Community contribution under heading B5-3 1 2 0 "European Agency for the Evaluation of Medicinal Products"

Since this is an autonomous body endowed with legal personality and possessing its own budget, the contribution from the Community budget is entered under Heading B5-312. The amount of this contribution is estimated on the basis of the costs referred to above and expected fee revenue.

The proposed new level and structure of fees aims at allowing the EMEA, in the long-term, to derive 75 percent of its revenues from fees, with the Community contribution falling to about 25 percent of total budget.

Although representing a gradually smaller proportion of total EMEA revenue, there is a continuing need for a Community contribution to cover the necessary public health and supervisory functions not carried out in the interest of specific companies (e.g. pharmacovigilance, technical harmonisation, etc.).

During the initial transition period, the Community contribution represented a substantial proportion of the total EMEA budget.

The projected EMEA budgetary perspectives show a clear trend to a reduction of the proportion from over one half to one quarter of the total budget. The proposed Regulation provides for a level and structure of fees which should permit this trend for the Community contribution to the current activities of the EMEA to be continued in the future.

8. FRAUD PREVENTION MEASURES

Council Regulation (EEC) No 2309/93 provides for specific adoption and budgetary control procedures. Each year the Management Board, composed of representatives of the Member States, Commission and Parliament, are responsible for adopting the draft budget (Article 55).

Current budgetary control mechanisms are described in Article 57, including the appointment of a financial controller by the Management Board and review of EMEA revenue and expenditure accounts by the Court of Auditors.

It should be noted that a draft Regulation is under preparation by the Commission which would transfer the financial control function for the EMEA to the Financial Controller of the Commission.

9. ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

9.1 Specific and quantifiable objectives

The provisions of Council Regulation (EEC) No 2309/93 setting up the new European registration system seek to promote the free movement of medicinal products in the Community, while at the same time providing better public health protection. In particular, it has been shown since the centralised procedure entered into force that the Regulation permits rapid access for new medicinal products to the single market and has ensured greater harmonisation of the conditions governing the placing on the market of medicinal products.

A single evaluation, meeting the highest possible scientific standards, is carried out by the EMEA, working in partnership with the Member States. The EMEA opinion forms the basis for the Commission decision-taking procedure for the granting of Community marketing authorisations.

Consequently, these provisions come under three major Community strategies:

- completion of the internal market in the pharmaceuticals sector
- industrial policy to promote the competitiveness of European research and development-based companies
- creation of a trans-European communications and early warning network linking the competent authorities, the EMEA and the Commission

9.2 Grounds for operation

The justifications made for Council Regulation (EC) No 297/95 continue to apply, namely that the new European authorisation system:

- prevents unnecessary duplication of scientific evaluation for products authorised through the centralised procedure by reducing the number of evaluations from 15 to 1
- reduces scope for conflicts between competent authorities through technical harmonisation
- accelerated evaluation permits pharmaceutical companies to make their products available more quickly, giving patients faster access to innovative medicines
- promotes the single market and free circulation of pharmaceuticals through the placing on the market of medicinal products under the same conditions throughout the EU

Even taking into account recent increases in the fees of Member State competent authorities, the level of fees payable to the EMEA for a Community marketing authorisation amount to about half the total corresponding fees payable to each of the fifteen national competent authorities.

The level of fees proposed do not place an excessive burden on the economic resources of undertakings in the sector. Research and development costs for a new molecule are generally estimated at ECU 200 million. The fees payable to the EMEA represent a very small proportion of this total.

Experience over the first two years show that in return for fees paid to the EMEA, applicants receive a service which is both rapid and effective. Thus allowing innovative new medicines to

be placed on the market more quickly than before - benefiting both patients and the European research and development-based industry. This also permits authorisation holders to begin to recover their costs earlier.

The amount of fees payable by applicants therefore appears modest and reasonable compared to fees payable at national level. It also represents an efficient means of financing the work of the EMEA, reducing the burden on the general budget of the Community.

9.3 Monitoring and evaluation of the operation

The principal performance indicators will continue to be:

- actual number of applications submitted by companies under the centralised procedure, taking into account the choice left open to undertakings
- level of post-marketing surveillance activity for centrally-authorised medicinal products and other Community referral procedures for nationally authorised products
- compliance with 300-day evaluation and decision-taking deadline by the EMEA and the Commission; the speed of the new system is a crucial factor for the European research and development based industry

Given the systematic use of the mutual recognition procedure for the majority of conventional medicines from the beginning of 1998, it is expected that there will be an increase in the number of arbitrations referred to the EMEA. This will also be an important performance indicator for the European authorisation system.

Evaluation:

- the EMEA Management Board adopts an annual report on the activities of the Agency which is forwarded to the Member States, Commission, Council and Parliament (Article 56 of Council Regulation (EEC) No 2309/93)
- the Executive Director of the EMEA is responsible for ensuring that time limits laid down for the adoption of opinions are respected (Article 55)
- at the initiative of the Executive Director, the Management Board has put in place a joint industry-regulators panel to review performance of the EMEA

An evaluation of the implementation of the proposed Regulation will be presented by the Commission within five years of its entry into force.

The Commission is also required to present a report on the overall implementation of the centralised and decentralised European registration systems within six years of the entry into force of Council Regulation (EEC) No 2309/93 (Article 71).

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