COMMISSION OF THE EUROPEAN COMMUNITIES

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2005/0023 (CNS)

Proposal for a

# COUNCIL REGULATION

## amending Regulation (EC) No 297/95 on fees payable to the European Medicines Agency

(presented by the Commission)

**{SEC(2005) 407}**

# EXPLANATORY MEMORANDUM

## 1. INTRODUCTION AND BACKGROUND

The pharmaceutical legislation has recently been revised. In this context, Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation, supervision and surveillance of medicinal products for human and veterinary use and establishing a European Medicines Agency[1] (EMEA, referred to as "the Agency") has been adopted by the Council and the European Parliament. It repeals Regulation (EEC) No 2309/93/EC.

As laid down in Article 67(3) of the Regulation, the Agency's revenue shall consist of a contribution from the Community and fees paid by undertakings for obtaining and maintaining Community marketing authorisations and for other services provided by the Agency[2].

It is acknowledged that the current fee scheme, as laid down in Council Regulation (EC) No 297/95 on fees payable to the EMEA[3], does neither take into account the new tasks of the Agency, nor the modifications of existing tasks introduced by the revised legislation. It is therefore necessary to amend it.

When drafting this proposal, the Commission has asked the EMEA to provide extensive feedback based on the experience gained with the application of the current system. In addition, a public consultation was held in July-September 2004, so as to take into account the position of relevant parties, in particular the pharmaceutical industry (see Section 2.4).

## 2. JUSTIFICATION

### 2.1. Objectives

Three major objectives have been pursued by the Commission in its proposal:

– To adapt the existing fee scheme to the revised legislation and the new responsibilities conferred to the Agency, taking in consideration the experience with the current system;

– To ensure proportionality between the amount of the fees and the nature of the service actually provided by the Agency;

– To alleviate the financial pressure put on applicants, without undermining the Agency's ability to perform its tasks.

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1 OJ L 136, 30.4.2004, p. 1.

2 Regulation (EC) No 726/2004, Article 67(3).

3 Council Regulation (EC) No 297/95 of 10 February 1995, OJ L 035 15.2.1995 p. 1, as amended by Council Regulation (EC) No 2743/98 of 14 December 1998, OJ L 345 19.12.98 p. 3 and by Commission Regulation (EC) No 494/2003 of 18 March 2003, OJ L 73 19.3.2003 p. 6.

## 2.2. Experience gained with the application of the current system

The EMEA has provided the Commission with an in-depth analysis of the operation of the current system[4]. Forward-looking perspectives, such as the consequences of the EU enlargement or the impact of the revision of the pharmaceutical legislation, were also taken in consideration. This analysis has led to the broad conclusion that the general principles, as well as the overall structure of the fees, have indeed enabled the Agency to fulfil its mission since 1995; they should therefore be maintained. Nevertheless, a number of key issues still require further optimisation.

Firstly, post-authorisation activities have taken an increasing part of the EMEA costs associated with the management of a medicinal product throughout its lifecycle. This is especially relevant for innovative medicines, which constitute the 'core business' of the Agency, and which often require special risk management strategies as well as tailor-made pharmacovigilance programmes. Such costs are not adequately covered by the corresponding fees, like the annual fee.

In addition, the Agency's revenues heavily depend on the payment of initial fees related to new applications. Despite the introduction of the annual fee in 1998, such dependence is still significant, and may hamper the EMEA's capability to perform long-term, multi-annual tasks, by affecting its financial stability.

In the field of veterinary medicines, experience suggests that the costs of service incurred for the evaluation of these products are of the same order of magnitude as those for medicinal products for human use. However, this has to be balanced with the very specific nature of the animal health market and the related issues. Such specificity should be taken into account in the proposal.

Finally, Council Regulation (EC) No 297/95, as amended, has given flexibility to the Management Board and to the Executive Director of the EMEA to adapt certain fees, under clearly-defined circumstances, to the particular situation of the application and the related product. Likewise, the use of graduated fees has also enabled to better reflect the actual level of scientific input and service provided. In the light of the abovementioned principle of proportionality, such flexibility could be further extended to other types of fees.

## 2.3. Impact of the revised pharmaceutical legislation

The revision of the pharmaceutical legislation has a direct impact on the Agency's mission and responsibilities. Regulation (EC) No 726/2004 provides for new tasks, as well as modifications of already-existing ones.

Post-authorisation activities have been substantially strengthened. For instance, the Agency has to record the status of marketing authorisations for medicinal products granted in accordance with Community procedures, by monitoring when and where products are actually marketed in the Member States, or cease to be[5]. Besides, the maintenance of marketing authorisation dossiers and of the various databases

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4 *Report to the European Commission on financing the European Agency for the Evaluation of Medicinal Products*, EMEA Management Board, March 2004.

5 Regulation (EC) No 726/2004, Article 13(4) and 38(4).

provided for in the legislation has to be managed by the Agency[6]. Finally, the risk-benefit balance of authorised medicinal products is subject to permanent follow-up[7].

Regulation (EC) No 726/2004 foresees new kinds of scientific services to be provided by the EMEA, such as the evaluation of traditional herbal medicinal products[8], or the assessment of applications for medicinal products intended exclusively for markets outside the Community, in the context of cooperation with the World Health Organisation[9]. New types of fees have therefore to be created, not only for these services but also for those which were not taken into account in the last revision of Council Regulation (EC) No 297/95, like the consultation on ancillary substances incorporated in medical devices[10], or the certification of plasma master files and vaccine antigen master files[11].

New provisions in Regulation (EC) No 726/2004 on generics and similar biological medicinal products[12] also call for the definition of related fees. In this respect, it is anticipated that the average cost for the assessment of similar biological medicinal products, although lower than for a full, stand-alone dossier, will still be significantly higher than for a standard generic.

Lastly, it is specified in the revised legislation that provisions shall be adopted by the Commission, establishing the circumstances in which small and medium-sized enterprises (SMEs) may pay reduced fees, defer payment of the fee, or receive administrative assistance[13]. Thus, the situation of SMEs has to be considered separately, *i.e.* outside the scope of the present proposal.

## 2.4. Outside consultation

Interested parties, in particular the pharmaceutical industry, have been consulted. In July 2004, the Commission launched an external consultation on its draft proposal, and received eight contributions from industry associations, regulators, and individual companies. Some of them, especially the ones from industry associations, were the result of wider, internal consultation. Contributions were carefully taken in consideration for the refinement of the Commission's draft.

The vast majority of respondents welcomed the proposal, the opportunity to comment, and explicitly supported the outlined objectives and key principles. In particular, the principle of proportionality between the fees, the corresponding services, and the related costs, was strongly emphasised.

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6 Regulation (EC) No 726/2004, Article 57(1)d and 57(1)l.
7 Regulation (EC) No 726/2004, Article 16(2) and 41(4).
8 Regulation (EC) No 726/2004, Article 62(1).
9 Regulation (EC) No 726/2004, Article 58.
10 In accordance with Council Directive No 93/42/EEC, as amended.
11 As defined in Directive No 2003/63/EC, Annex I, Part III, Sections 1.1 and 1.2.
12 Directive 2001/83/EC as amended by Directive 2004/27/EC, Article 10(4).
13 Regulation (EC) No 726/2004, Article 70(2).

## 3. PRESENTATION OF THE PROPOSAL

*A comparison of the current fees vs. the proposal, including references to the relevant Articles, is annexed to the Explanatory Memorandum.*

In view of the abovementioned considerations, the general structure of the fees and the underlying principles have not been changed. Moreover, given the increase that was already implemented in March 2003, most of the fees have been kept to the same level, or slightly reduced.

### 3.1. Annual fee

As mentioned in Section 2.2, costs related to post-authorisation activities are, at present, not appropriately covered. If no action is taken, this discrepancy could increase with the entering into force of the revised legislation and the new responsibilities of the Agency. While it is required by law that activities relating to pharmacovigilance and to market surveillance shall receive adequate public funding commensurate with the tasks conferred[14], such funding alone may not be sufficient to fully cover administrative costs described in Section 2.3, *e.g.* maintaining up-to-date marketing authorisation dossiers and the various databases. Besides, the EMEA's financial stability is affected by its dependence on initial fees linked to new applications. For these reasons, it is hence proposed to increase the annual fee, both in the human and veterinary sectors, by 10%.

### 3.2. Medicinal products for human use

Most of the fees for services related to medicinal products for human use have been kept to the same level. In addition to the annual fee increase (see Section 3.1), it is suggested:

– to reduce the fee for generic medicinal products, in order to better reflect the actual cost of the evaluation of the marketing authorisation application;

– to harmonise extension fees, Type II variation fees, and fees associated with the submission of additional presentations of a given medicinal product;

– to reduce the fee for Type IA variations, so as to better reflect the administrative nature of the service provided.

### 3.3. Veterinary medicinal products

Taking into account the specific nature of the animal health market and the commercial and regulatory environment in which the related companies evolve, it is proposed to keep all fees related to veterinary medicinal products to the same level, apart from the annual fee (see Section 3.1), and the fee for Type IA variations, which has been reduced for the reason outlined above.

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[14] Regulation (EC) No 726/2004, Article 67(4).

### 3.4. Scientific services

New types of fees have been defined for a wide range of scientific services provided by the Agency. These are related to (see Section 2.3):

– opinions on traditional herbal medicinal products;

– assessment of applications for medicinal products intended exclusively for markets outside the Community, in the context of cooperation with the World Health Organisation.

– consultation of the Committees on ancillary substances, including blood derivatives, incorporated in medical devices;

– evaluation and certification of plasma master files and vaccine antigen master files;

Experience acquired by the EMEA on these services has shown that they can lead to the mobilisation of significant scientific, administrative and financial resources. This is further reflected by the proposed levels of the fees.

### 3.5. Other provisions

As already laid down in Council Regulation (EC) No 297/95, substantial flexibility has been given to the Management Board and the Executive Director of the EMEA for the practical implementation of this Regulation. In particular, the option to draw-up detailed lists of reduced fees for certain services, under well-defined conditions, has been extended to other fee categories.

As mentioned in Section 2.3, a specific fee has been defined for similar biological medicinal products. The calculation of the fee is based on the complex nature of these medicines, the expected costs for the dossier evaluation, and the particular status of this emerging and fast-growing market.

Regarding due date and belated payment, the time period within which fees shall be payable has been extended from 30 to 45 days. Moreover, a special deferral rule has been proposed for applications concerning medicines to be used in human pandemic situations (such as pandemic influenza vaccines).

Finally, an indexation clause has been introduced, in order to easily adapt the fees to inflation variations.

| *(in Euros)* | | Current | | Proposal | Dif. | Ref. |
|---|---|---|---|---|---|---|
| **Human** | | | | | | |
| **Full fee** | base | 232000 | | 232000 | 0% | Art. 3(1)(a) |
| | addit. strength/form | 23200 | | 23200 | 0% | Art. 3(1)(a) |
| | addit. presentation | 5800 | | 5800 | 0% | Art. 3(1)(a) |
| **Reduced fee** | base | 116000 | generic | 90000 | **-22%** | Art. 3(1)(b) |
| | | | bio-similar | 150000 | **NEW** | Art. 3(1)(b) |
| | addit. strength/form | 23200 | | 9000 | **-61%** | Art. 3(1)(b) |
| | addit. presentation | 5800 | | 5800 | 0% | Art. 3(1)(b) |
| | | | | | | |
| **Extension fee** | new strength/form etc. | 58000 | max | 69600 | **20%** | Art. 3(1)(c) |
| | new presentation | 11600 | | 5800 | **-50%** | Art. 3(1)(c) |
| **Type I variation** | | 5800 | IA | 2500 | **-57%** | Art. 3(2)(a) |
| | | | IB | 5800 | 0% | Art. 3(2)(a) |
| **Type II variation** | | 69600 | max | 69600 | 0% | Art. 3(2)(b) |
| | | | | | | |
| **Renewal** | | 11600 | | 11600 | 0% | Art. 3(3) |
| **Inspection** | | 17400 | max | 17400 | 0% | Art. 3(4) |
| **Transfer** | | 5800 | | 5800 | 0% | Art. 3(5) |
| **Annual fee** | | 75600 | max | 83200 | **10%** | Art. 3(6) |
| **Referral** | | 58000 | | 58000 | 0% | Art. 4 |
| | | | | | | |
| **Scientific advice** | | 69600 | max | 69600 | 0% | Art. 8(1) |
| **Scientific services** | | | max | 232000 | **NEW** | Art. 8(2) |
| **Administrative services** | | 5800 | max | 5800 | 0% | Art. 8(3) |

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|---|---|---|---|---|---|---|
| **Veterinary** | | | | | | |
| **Full fee** | base | 116000 | | 116000 | 0% | Art. 5(1)(a) |
| | addit. strength/form | 11600 | | 11600 | 0% | Art. 5(1)(a) |
| | addit. presentation | 5800 | | 5800 | 0% | Art. 5(1)(a) |
| **Full fee vaccines** | vaccines | 58000 | immunologicals | 58000 | 0% | Art. 5(1)(a) |
| | addit. strength/form/pres. | 5800 | | 5800 | 0% | Art. 5(1)(a) |
| **Reduced fee** | base | 58000 | generic | 58000 | 0% | Art. 5(1)(b) |
| | | | bio-similar | 98000 | **NEW** | Art. 5(1)(b) |
| | addit. strength/form | 11600 | | 11600 | 0% | Art. 5(1)(b) |
| | addit. presentation | 5800 | | 5800 | 0% | Art. 5(1)(b) |
| **Reduced fee vaccines** | vaccines | 29000 | immunologicals | 29000 | 0% | Art. 5(1)(b) |
| | addit. strength/form/pres. | 5800 | | 5800 | 0% | Art. 5(1)(b) |

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|---|---|---|---|---|---|---|
| | | | | | | |
| **Extension fee** | new strength/form etc. | 29000 | max | 29000 | 0% | Art. 5(1)c |
| | new presentation | 5800 | | 5800 | 0% | Art. 5(1)c |
| | vaccines | 5800 | (vaccines | 5800 | 0% | Art. 5(1)c |
| **Type I variation** | | 5800 | IA | 2500 | **-57%** | Art. 5(2)(a) |
| | | | IB | 5800 | 0% | Art. 5(2)(a) |
| **Type II variation** | | 34800 | max | 34800 | 0% | Art. 5(2)(b) |
| | vaccines | 5800 | | 5800 | 0% | Art. 5(2)(b) |
| | | | | | | |
| **Renewal** | | 5800 | | 5800 | 0% | Art. 5(3) |
| **Inspection** | | 17400 | max | 17400 | 0% | Art. 5(4) |
| **Transfer** | | 5800 | | 5800 | 0% | Art. 5(5) |
| **Annual fee** | | 25200 | max | 27700 | **10%** | Art. 5(6) |
| **Referral** | | 34800 | | 34800 | 0% | Art. 6 |
| **MRL fee** | base | 58000 | | 58000 | 0% | Art. 7 |
| | amend/extend existing | 17400 | | 17400 | 0% | Art. 7 |
| | clinical trials | 17400 | | 17400 | 0% | Art. 7 |
| | | | | | | |
| **Scientific Advice** | | 34800 | max | 34800 | 0% | Art. 8(1) |
| **Scientific services** | | | max | 116000 | **NEW** | Art. 8(2) |
| **Administrative services** | | 5800 | max | 5800 | 0% | Art. 8(3) |

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Proposal for a

# COUNCIL REGULATION

## amending Regulation (EC) No 297/95 on fees payable to the European Medicines Agency

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[15], and in particular Article 12 thereof,

Having regard to the proposal from the Commission[16],

Having regard to the opinion of the European Parliament[17],

Whereas:

(1) Article 67(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation, supervision and surveillance of medicinal products for human and veterinary use and establishing a European Medicines Agency[18], stipulates that the revenue of the European Medicines Agency (hereinafter referred to as 'the Agency') shall consist of a contribution from the Community and fees paid by undertakings for obtaining and maintaining Community marketing authorisations and for other services provided by the Agency.

(2) Regulation (EC) No 726/2004 also provides for new tasks for the Agency. Furthermore, the existing tasks have also been changed following amendments to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[19], and to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[20].

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15 OJ L 35, 15.2.1995, p. 1. Regulation as last amended by Commission Regulation (EC) No 494/2003 (OJ L 73 19.3.2003 p. 6).

16 OJ C , , p. .

17 OJ C , , p. .

18 OJ L 136, 30.4.2004, p. 1.

19 OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

20 OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

(3) 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 Regulation (EC) No 297/95; in particular, the calculation of the level of fees charged by the Agency should be based on the principle of the service actually provided and should be related to specific medicinal products. The proportionality between the fees and the assessment related costs of each application, as well as the provision of the service requested, should also be ensured.

(4) Regulation (EC) No 726/2004 lays down provisions for new post-authorisation activities to be carried out by the Agency. These tasks include the recording of the actual marketing of medicinal products authorised in accordance with Community procedures, the maintenance of marketing authorisation dossiers and of the various databases managed by the Agency, as well as the continuous follow-up of the risk-benefit balance of authorised medicinal products. In addition, it is necessary to reduce the Agency's dependence on fees related to new applications. The annual fee should therefore be increased by 10% to accommodate those changes.

(5) New categories of fees have to be created to cover new, specific tasks now provided by the Agency, such as new types of scientific opinions related to a medicinal product.

(6) The Management Board of the Agency should be competent to specify provisions necessary for the application of this Regulation, on a proposal from the Executive Director and following a favourable opinion from the Commission. In particular, the Management Board should establish, for certain services where the level of the corresponding fee is set as a maximum, detailed classifications and lists of reduced fees.

(7) The Executive Director should also keep the competence to decide, in exceptional circumstances, on reductions of the fees, in particular as regards certain cases related to specific medicinal products and where a reduction is necessary for imperative reasons of public or animal health. Likewise, the Executive Directive should have the possibility to decide on exemptions from the obligation to pay a fee in the case of medicinal products for the treatment of rare diseases, for the treatment of diseases affecting minor animal species and for the addition of animal species in the case of the determination of maximum residue limits in accordance with the procedure laid down in Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin[21].

(8) In accordance with Article 70(2) of Regulation (EC) No 726/2004, the circumstances under which small and medium-sized enterprises may pay reduced fees, defer payment of the fee or receive administrative assistance are not to be covered by this Regulation.

(9) In order to allow an immediate budgetisation, the fees should be due on the date of validation but should be payable within a certain number of days.

(10) Provisions should be laid down to report on the implementation of this Regulation after experience has been gained and to review, if necessary, the level of the fees.

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[21] OJ L 224, 18.8.1990, p.1. Regulation as last amended by Commission Regulation (EC) No 1875/2004 (OJ L 326, 29.10.2004, p. 19).

(11) It is appropriate to include an indexation mechanism for automatically adjusting the fees in relation to official inflation rates indices.

(12) For the sake of consistency, this Regulation should apply at the same time as the full entering into force of Regulation (EC) No 726/2004. It should not apply to valid applications pending at the time of its application.

(13) Regulation (EC) No 297/95 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

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

(1) In the second paragraph of Article 1 "ecus" is replaced by "euros".

(2) Article 3 is amended as follows:

(a) In the title "Regulation (EEC) No 2309/93" is replaced by "Regulation (EC) No 726/2004 of the European Parliament and of the Council*

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* OJ L 136, 30.4.2004, p. 1".

(b) Paragraph 1 is amended as follows:

(i) Point (a) is amended as follows:

– The first subparagraph is replaced by the following:

"A full fee of EUR 232 000 shall apply for an application for a marketing authorisation supported by a full dossier. That fee shall cover a single strength associated with one pharmaceutical form and one presentation."

– The second sentence of the second subparagraph is replaced by the following:

"That increase shall cover one additional strength or pharmaceutical form and one presentation."

(ii) Points (b) and (c) are replaced by the following:

"(b) Reduced fee

A reduced fee of EUR 90 000 shall apply to applications for a marketing authorisation pursuant to Articles 10(1), 10(3) and 10c of Directive 2001/83/EC of the European Parliament and of the Council**. That fee shall cover a single strength associated with

one pharmaceutical form and one presentation.

A specific reduced fee of EUR 150 000 shall apply to applications for a marketing authorisation pursuant to Article 10(4) of Directive 2001/83/EC. That fee shall cover a single strength associated with one pharmaceutical form and one presentation.

The reduced fees referred to in the first and second subparagraph shall be increased by EUR 9 000 for each additional strength or pharmaceutical form submitted at the same time as the initial application for authorisation. That increase shall cover one additional strength or pharmaceutical form and one presentation.

The reduced fees referred to in the first and second subparagraph shall be increased by 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

An extension fee of EUR 69 600 shall apply for each extension of a marketing authorisation within the meaning of Annex II to Commission Regulation (EC) No 1085/2003***, which has already been granted.

A reduced extension fee falling within the range of EUR 17 400 to EUR 52 200 shall apply for certain extensions. Those extensions shall be included in a list, which shall be drawn up in accordance with Article 11(2).

The extension fee and the reduced extension fee shall be increased by EUR 5 800 for each additional presentation of the same extension submitted at the time of the extension application.

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** OJ L 311, 28.11.2001, p. 67.

*** OJ L 159, 27.06.2003, p. 24."

(c) Paragraph 2 is amended as follows:

(i) In point (a) the first subparagraph is replaced by the following:

"A Type I variation fee shall apply for a minor variation to a marketing authorisation, as defined in Article 3(2) of Regulation (EC) No 1085/2003. For Type IA variations, the fee shall be EUR 2 500. For Type IB variations, the fee shall be EUR 5 800."

(ii) In point (b) the first subparagraph is replaced by the following:

"A Type II variation fee of EUR 69 600 shall apply for a major variation to a marketing authorisation, as defined in Article 3(3) of Regulation (EC) No 1085/2003.

A reduced Type II variation fee falling within the range of EUR 17 400 to EUR 52 200 shall apply for certain variations. Those variations shall be included in a list, which shall be drawn up in accordance with Article 11(2)."

(d) In paragraph 4 the following subparagraph is added:

"The inspection fee shall differ according to the extent and nature of the inspection and on the basis of the conditions laid down in accordance with Article 11(2)."

(e) Paragraph 6 is replaced by the following:

"6. Annual fee

An annual fee of EUR 83 200 shall apply for each marketing authorisation of a medicinal product. That fee shall cover all authorised presentations of a given medicinal product.

A reduced annual fee falling within the range of EUR 20 800 to EUR 62 400 shall apply for certain types of medicinal products. Those medicinal products shall be included in a list, which shall be drawn up in accordance with Article 11(2)."

(3) Article 4 is replaced by the following:

"Article 4

**Medicinal products for human use covered by the procedures laid down in Directive 2001/83/EC**

Referral fee

A referral fee of EUR 58 000 shall apply where the procedures laid down in Articles 30(1) and 31 of Directive 2001/83/EC are initiated by the applicant of a marketing authorisation or the holder of an existing marketing authorisation.

Where more than one applicant of marketing authorisations or holder of existing marketing authorisations are concerned by the procedures referred to in the first subparagraph, the applicants or holders may be grouped for the purpose of the payment of one single referral fee. If however, the same procedure concerns more than 10 different applicants or holders, the fee will be charged by the application of a flat-rate fee."

(4) Article 5 is amended as follows:

(a) In the title "Regulation (EEC) No 2309/93" is replaced by "Regulation (EC) No 726/2004".

(b) Paragraph 1 is amended as follows:

(i) Point (a) is amended as follows:

– The first subparagraph is replaced by the following:

"A full fee of EUR 116 000 shall apply for an application for a marketing authorisation supported by a full dossier. That fee shall cover a single strength associated with one pharmaceutical form and one presentation."

– The second sentence of the second subparagraph is replaced by the following:

"That increase shall cover one additional strength or pharmaceutical form and one presentation."

– In the fourth subparagraph, "vaccines" is replaced by "immunological veterinary medicinal products".

(ii) Point (b) is replaced by the following:

"A reduced fee of EUR 58 000 shall apply to applications for a marketing authorisation pursuant to Articles 13(1), 13(3) and 13c of Directive 2001/82/EC of the European Parliament and of the Council****. That fee shall cover a single strength associated with one pharmaceutical form and one presentation.

A specific reduced fee of EUR 98 000 shall apply to applications for a marketing authorisation pursuant to Article 13(4) of Directive 2001/82/EC. That fee shall cover a single strength associated with one pharmaceutical form and one presentation.

The reduced fees referred to in the first and second subparagraph shall be increased by EUR 11 600 for each additional strength or pharmaceutical form submitted at the same time as the initial application for authorisation. That increase shall cover one additional strength or pharmaceutical form and one presentation.

The reduced fees referred to in the first and second subparagraph shall be increased by 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 immunological veterinary medicinal products, the fee shall

be reduced to EUR 29 000, with each additional strength and/or pharmaceutical form and/or presentation entailing an increase of EUR 5 800.

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

**** OJ L 311, 28.11.2001, p. 1."

(iii) Point (c) is replaced by the following:

"(c) Extension fee

An extension fee of EUR 29 000 shall apply for each extension of a marketing authorisation within the meaning of Annex II to Regulation (EC) No 1085/2003, which has already been granted.

A reduced extension fee falling within the range of EUR 7 200 to EUR 21 700 shall apply for certain extensions. Those extensions shall be included in a list, which shall be drawn up in accordance with Article 11(2).

The extension fee and the reduced extension fee shall be increased by EUR 5 800 for each additional presentation of the same extension submitted at the time of the extension application."

(c) Paragraph 2 is amended as follows:

(i) In point (a) the first subparagraph is replaced by the following:

"A Type I variation fee shall apply for a minor variation to a marketing authorisation, as defined in Article 3(2) of Commission Regulation (EC) No 1085/2003. For Type IA variations, the fee shall be EUR 2 500. For Type IB variations, the fee shall be EUR 5 800."

(ii) Point (b) is replaced by the following:

"A Type II variation fee of EUR 34 800 shall apply for a major variation to a marketing authorisation, as defined in Article 3(3) of Regulation (EC) No 1085/2003.

A reduced Type II variation fee falling within the range of EUR 8 700 to EUR 26 100 shall apply for certain variations. Those variations shall be included in a list, which shall be drawn up in accordance with Article 11(2).

In the case of immunological veterinary medicinal products, the fee shall be EUR 5 800.

In the event of the same variation being introduced, the fee referred to in

the first, second and third subparagraph shall cover all authorised strengths, pharmaceutical forms and presentations."

(d) In paragraph 4 the following subparagraph is added:

"The inspection fee shall differ according to the extent and nature of the inspection and on the basis of the conditions laid down in accordance with Article 11(2)."

(e) Paragraph 6 is replaced by the following:

"6. Annual fee

An annual fee of EUR 27 700 shall apply for each marketing authorisation of a medicinal product. That fee shall cover all authorised presentations of a given medicinal product.

A reduced annual fee falling within the range of EUR 6 900 to EUR 20 800 shall apply for certain types of medicinal products. Those medicinal products shall be included in a list, which shall be drawn up in accordance with Article 11(2)."

(5) Article 6 is replaced by the following:

"*Article 6*

**Veterinary medicinal products covered by the procedures laid down in Directive 2001/82/EC**

*Referral fee*

A referral fee of EUR 34 800 shall apply where the procedures laid down in Articles 34(1) and 35 of Directive 2001/82/EC are initiated by the applicant of a marketing authorisation or the holder of an existing marketing authorisation.

Where more than one applicant of marketing authorisations or holder of existing marketing authorisations are concerned by the procedures referred to in the first subparagraph, the applicants or holders may be grouped for the purpose of the payment of one single referral fee. If however, the same procedure concerns more than 10 different applicants or holders, the fee will be charged by the application of a flat-rate fee."

(6) Article 7 is amended as follows:

(a) In the title, "for veterinary medicinal products" is replaced by "for veterinary medicinal products in accordance with the procedures laid down in Council Regulation (EEC) No 2377/90*****

*****OJ L 224, 18.8.1990, p. 1."

(b) In paragraph 1 the second subparagraph is replaced by the following:

"An additional fee of EUR 17 400 shall apply for each application to modify an existing MRL, as included in one of the Annexes to Regulation (EEC) No 2377/90."

(c) Paragraph 2 is deleted.

(7) Article 8 is replaced by the following:

"*Article 8*

**Various Fees**

*1. Fee for scientific advice*

The scientific advice fee shall apply where an application is made for scientific advice concerning the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products.

When it concerns medicinal products for human use, the fee shall be EUR 69 600.

When it concerns veterinary medicinal products, the fee shall be EUR 34 800.

A reduced scientific advice fee falling within the range of EUR 17 400 to EUR 52 200 shall apply for certain scientific advice concerning medicinal products for human use.

A reduced scientific advice fee falling within the range of EUR 8 700 to EUR 26 100 shall apply for certain scientific advice concerning veterinary medicinal products.

The scientific advice referred to in the fourth and fifth subparagraph shall be included in a list, which shall be drawn up in accordance with Article 11(2).

*2. Fee for scientific services not covered by Articles 3 to 7 or by Article 8(1)*

A scientific service fee shall apply where an application is made for any scientific advice or opinion by a scientific Committee, which is not covered by Articles 3 to 7 or by Article 8(1). This includes any evaluation of traditional herbal medicinal products, any opinion on medicinal products for compassionate use, any consultation on ancillary substances, including blood derivatives, incorporated in medical devices, and any evaluation of plasma master files and vaccine antigen master files.

When it concerns medicinal products for human use, the fee shall be EUR 232 000.

When it concerns veterinary medicinal products, the fee shall be EUR 116 000.

The provisions of Article 3 shall apply to any scientific opinion for the evaluation of medicinal products for human use intended exclusively for markets outside the Community pursuant to Article 58 of Regulation (EC) No 726/2004.

A reduced scientific service fee falling within the range of EUR 2 500 to EUR 200 000 shall apply for certain scientific opinions or services concerning medicinal products for human use.

A reduced scientific service fee falling within the range of EUR 2 500 to EUR 100 000 shall apply for certain scientific opinions or services concerning veterinary medicinal products.

The scientific opinions or services referred to in the fifth and sixth subparagraph shall be included in a list, which shall be drawn up in accordance with Article 11(2).

*3. Fee for administrative services*

A fee falling within the range of EUR 100 to EUR 5 800 shall apply for administrative services where documents or certificates are issued outside the framework of services covered by another fee provided for in this Regulation or where an application is rejected following the conclusion of the administrative validation of the related dossier or where the information required in the case of parallel distribution has to be checked.

A classification of the services and fees shall be included in a list, which shall be drawn up in accordance with Article 11(2).”

(8) In Article 9 the second paragraph is replaced by the following:

“A total or partial exemption from payment of the fees laid down in this Regulation may be granted, in particular for medicinal products for treating rare diseases or diseases affecting minor animal species or for extension of existing MRL to additional animal species or for medicinal products available for compassionate use.

The detailed conditions for the application of the total or partial exemption shall be determined in accordance with Article 11(2).

The fee payable for an opinion on a medicinal product for compassionate use shall be deduced from the fee payable for an application for a marketing authorisation of the same medicinal product, where such application is submitted by the same applicant.”

(9) Article 10 is replaced by the following:

“*Article 10*

**Due date and deferral of the payment**

1. Fees shall be due on the date of the administrative validation of the relevant application unless specific provisions stipulate otherwise. They shall be payable within 45 days of the date of the notification of the administrative validation to the applicant. They shall be paid in Euros.

The annual fee shall be due on the first and each subsequent anniversary of the notification of the marketing authorisation decision. It shall be payable within 45 days of the due date. The annual fee shall relate to the preceding year.

The inspection fee shall be payable within 45 days from the date on which the inspection is carried out.

2. The payment of the fee for an application for a marketing authorisation of a medicinal product to be used in a human pandemic situation shall be deferred until the pandemic situation is duly recognised, either by the World Health Organisation or by the Community in the framework of Decision 2119/98/EC of the European Parliament and of the Council******. Such deferral shall not exceed five years.

3. 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 71 of Regulation (EC) No 726/2004, the Executive Director may decide not to provide the requested services or to suspend all the services and procedures under way until the fee has been paid, including the relevant interest as provided for in Article 86 of Commission Regulation (EC, Euratom) No 2342/2002*******.

****** OJ L 268, 3.10.1998, p.1.

******* OJ L 357, 31.12.2002, p.1."

(10) In Article 11 paragraph 2 is replaced by the following:

"2. Without prejudice to the provisions of Regulation (EC) No 726/2004, the Management Board of the Agency may, on a proposal from the Executive Director and following a favourable opinion from the Commission, specify any provision necessary for the application of this Regulation."

(11) Article 12 is amended as follows:

(a) In the second paragraph, "Article 73 of Regulation (EEC) No 2309/93" is replaced by "Article 87(2) of Regulation (EC) No 726/2004, with exception of the updating provided for in the fifth paragraph of this Article."

(b) The third and fourth paragraphs are replaced by the following:

"Within five years of the entry into force of this Regulation, the Commission shall present a report on its implementation to the Council.

Any review of the fees shall be based on an evaluation of the Agency's costs and on the basis of the related costs of the services provided for by the Member States. Those costs shall be calculated in accordance with generally accepted international costing methods."

(c) The following fifth paragraph is added:

"With effect from 1 April of each year, the Commission shall review the fees by reference to the inflation rate as published in the Official Journal of the European Union and update them. "

*Article 2*
*Transitional period*

This Regulation shall not apply to valid applications pending at 20 November 2005.

*Article 3*
*Entry into force*

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

It shall apply from 20 November 2005.

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

Done at Brussels,

*For the Council*
*The President*

## LEGISLATIVE FINANCIAL STATEMENT

**Policy area(s): Internal Market (Article 95 TEC).**

**Activit(y/ies): The activities of the European Medicines Agency are included in the following policies:**

**- Improving the protection of public health across the Community;**

**- Maintaining a reliable and independent source of scientific advice and information on medicinal products;**

**- Supporting the achievement of the internal market for the pharmaceutical sector.**

**Title of action: PROPOSAL FOR A COUNCIL REGULATION AMENDING COUNCIL REGULATION (EC) No 297/95 ON FEES PAYABLE TO THE EUROPEAN MEDICINES AGENCY (EMEA)**

### 1. BUDGET LINE(S) + HEADING(S)

02.040201 – European Agency for the Evaluation of Medicinal Products — Subsidy under Titles 1 and 2

02.040202 – European Agency for the Evaluation of Medicinal Products — Subsidy under Title 3

### 2. OVERALL FIGURES

### 2.1. Total allocation for action (Part B): € million for commitment

### 2.2. Period of application:

The proposed Regulation should apply from 20 November 2005. The overall impact on revenues has been calculated for 2005-2010 and indicates a rough increase of the gross revenues of the Agency from 2 to 4 million euro per year. Nevertheless, additional costs resulting from the new tasks provided to the Agency by Regulation (EC) No 726/2004 have not yet been fully assessed. As a consequence, the effect on the level of subsidy from the UE budget can only be evaluated in a further stage.

The detailed results of the calculation of revenues are provided in Section 10: Annex of the Legislative Financial Statement.

## 2.3. Overall multiannual estimate of expenditure:

(a) Schedule of commitment appropriations/payment appropriations (financial intervention) *(see point 6.1.1)*

€ million (*to three decimal places)*

| | Year [n] | [n+1] | [n+2] | [n+3] | [n+4] | [n+5 and subs. Years] | Total |
|---|---|---|---|---|---|---|---|
| Commitments | | | | | | | |
| Payments | | | | | | | |

(b) Technical and administrative assistance and support expenditure*(see point 6.1.2)*

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Commitments | | | | | | | |
| Payments | | | | | | | |

| Subtotal a+b | | | | | | | |
|---|---|---|---|---|---|---|---|
| Commitments | | | | | | | |
| Payments | | | | | | | |

(c) Overall financial impact of human resources and other administrative expenditure *(see points 7.2 and 7.3)*

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Commitments/ payments | | | | | | | |

| TOTAL a+b+c | | | | | | | |
|---|---|---|---|---|---|---|---|
| Commitments | | | | | | | |
| Payments | | | | | | | |

## 2.4. Compatibility with financial programming and financial perspective

[X] Proposal is compatible with existing financial programming.

Proposal will entail reprogramming of the relevant heading in the financial perspective.

Proposal may require application of the provisions of the Interinstitutional Agreement.

## 2.5. Financial impact on revenue:[22]

[X] Proposal has no financial implications (involves technical aspects regarding implementation of a measure)

OR

Proposal has financial impact – the effect on revenue is as follows:

***(NB All details and observations relating to the method of calculating the effect on revenue should be shown in a separate annex.)***

(€ million to one decimal place)

| | | Prior to action | Situation following action | | | | | |
|---|---|---|---|---|---|---|---|---|
| Budget line | Revenue | [Year n-1] | [Year n] | [n+1] | [n+2] | [n+3] | [n+4] | [n+5] |
| | *a) Revenue in absolute terms* | | | | | | | |
| | *b) Change in revenue* | *Δ* | | | | | | |

***(Please specify each budget line involved, adding the appropriate number of rows to the table if there is an effect on more than one budget line.)***

## 3. BUDGET CHARACTERISTICS

| **Type of expenditure** | | **New** | **EFTA contribution** | **Contributions form applicant countries** | **Heading in financial perspective** |
|---|---|---|---|---|---|
| Non-comp | Non-diff | NO | YES | NO | **No 3 (1a)** |

## 4. LEGAL BASIS

As laid down in Article 67(3) of Regulation (EC) No 726/2004, the Agency's revenue shall consist of a contribution from the Community and fees paid by undertakings for obtaining and maintaining Community marketing authorisations and for other services provided by the Agency .

The current amounts and structure of the fees are laid down in Council Regulation (EC) No 297/95, of 10 February 1995, on fees payable to the European Agency for the Evaluation of Medicinal Products. There is hence a clear legal basis for Community action.

[22] For further information, see separate explanatory note.

## 5. DESCRIPTION AND GROUNDS

Details of the context of the proposal are given in the Explanatory Memorandum.

### 5.1. Need for Community intervention [23]

*5.1.1. Objectives pursued*

(For more details, see Section 2 of the Explanatory Memorandum.)

The main objectives of the proposal are:

- To adapt the existing fee scheme to the revised pharmaceutical legislation and the new responsibilities conferred to the EMEA, taking in consideration the experience with the current system;

- To ensure proportionality between the amount of the fees and the nature of the service actually provided by the Agency;

- To alleviate the financial pressure put on applicants, without undermining the Agency's ability to perform its tasks.

The proposal's objectives contribute to the three strategic goals of the Community framework for the authorisation, supervision and surveillance of medicinal products, and the establishment of the European Medicines Agency, *i.e.*:

- Protecting public health across the Community;

- Maintaining a reliable and independent source of scientific advice and information on medicinal products;

- Supporting the achievement of the internal market for the pharmaceutical sector.

*5.1.2. Measures taken in connection with ex ante evaluation*

(For more details, see the Impact Assessment and Sections 2.3 & 2.4 of the Explanatory Memorandum.)

Firstly, an Impact Assessment, which accompanies this Financial Statement, was conducted on the Commission's proposal. It primarily draws on experience with the existing EU pharmaceutical market and regulatory framework, experience with the current fees scheme, extensive consultation with stakeholders (in particular industry associations, see below), and feedback from the EMEA.

Secondly, the Commission launched in July 2004 an external consultation on its draft proposal, and received numerous contributions from industry associations, regulators, and individual companies. Some of them, especially the ones from industry associations, were the result of wider, internal consultation. Contributions were carefully taken in consideration for the refinement of the Commission's draft.

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[23] For further information, see separate explanatory note.

*5.1.3. Measures taken following* ex post *evaluation*

(For more details, see Section 2.2 of the Explanatory Memorandum)

The EMEA has provided the Commission with an in-depth analysis of the operation of the current fee system[24]. Such analysis has led to three main conclusions:

- The general principles, as well as the overall structure of the fees, have indeed enabled the Agency to fulfill its mission since 1995; they should therefore be maintained. Thus, most of the fees should not be changed.

- In order to adequately cover post-marketing costs and to reduce the Agency's revenues dependence on the payment of initial fees related to new applications, it appears necessary to increase the annual fee.

- In order to ensure flexibility and to better reflect the actual level of scientific input and service provided, the use of graduated fees should be extended.

## 5.2. Action envisaged and budget intervention arrangements

Achievement of the objectives and expected results can easily be measured, for instance in terms of:

-Number of medicinal products subject to a scientific evaluation by the EMEA;

-Number of products granted a Community marketing authorisation and placed on the market;

-Number of scientific advices given for products in the development phase;

-Number of requests for post-marketing studies, pharmacovigilance plans and risk management systems, and the delivery against those plans;

-Number of variations applications and line extensions applications submitted to the Agency;

-Number of arbitration and Community referrals made to the EMEA;

etc.

## 5.3. Methods of implementation

Centralised Management, indirectly by delegation to a body set up by the Communities as referred to in art. 185 of the Financial Regulation (EMEA)

[24] *Report to the European Commission on financing the European Agency for the Evaluation of Medicinal Products*, EMEA Management Board, March 2004.

## 6. FINANCIAL IMPACT

### 6.1. Total financial impact on Part B - (over the entire programming period)

*(The method of calculating the total amounts set out in the table below must be explained by the breakdown in Table 6.2. )*

*6.1.1. Financial intervention*

Commitments (in € million to three decimal places)

| Breakdown | [Year n] | [n+1] | [n+2] | [n+3] | [n+4] | [n+5 and subs. Years] | Total |
|---|---|---|---|---|---|---|---|
| Action 1 | | | | | | | |
| Action 2 | | | | | | | |
| etc. | | | | | | | |
| **TOTAL** | | | | | | | |

*6.1.2. Technical and administrative assistance, support expenditure and IT expenditure (commitment appropriations)*

| | [Year n] | [n+1] | [n+2] | [n+3] | [n+4] | [n+5 and subs. years] | Total |
|---|---|---|---|---|---|---|---|
| 1) Technical and administrative assistance | | | | | | | |
| a) Technical assistance offices | | | | | | | |
| b) Other technical and administrative assistance:<br>- intra muros:<br>- extra muros:<br>*of which for construction and maintenance of computerised management systems* | | | | | | | |
| Subtotal 1 | | | | | | | |
| 2) Support expenditure | | | | | | | |
| a) Studies | | | | | | | |
| b) Meetings of experts | | | | | | | |
| c) Information and publications | | | | | | | |
| Subtotal 2 | | | | | | | |
| **TOTAL** | | | | | | | |

### 6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)[25]

*(Where there is more than one action, give sufficient detail of the specific measures to be taken for each one to allow the volume and costs of the outputs to be estimated.)*

Commitments (in € million to three decimal places)

| Breakdown | Type of outputs (projects, files ) | Number of outputs (total for years 1…n) | Average unit cost | Total cost (total for years 1…n) |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4=(2X3) |
| Action 1 | | | | |
| - *Measure 1* | | | | |
| - *Measure 2* | | | | |
| Action 2 | | | | |
| - *Measure 1* | | | | |
| - *Measure 2* | | | | |
| - *Measure 3* | | | | |
| *etc.* | | | | |
| TOTAL COST | | | | |

*If necessary explain the method of calculation*

## 7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

### 7.1. Impact on human resources

| Types of post | | Staff to be assigned to management of the action using existing and/or additional resources | | Total | Description of tasks deriving from the action |
|---|---|---|---|---|---|
| | | Number of permanent posts | Number of temporary posts | | |
| Officials or temporary staff | A<br>B<br>C | | | | *If necessary, a fuller description of the tasks may be annexed.* |
| Other human resources | | | | | |
| Total | | | | | |

[25] For further information, see separate explanatory note.

### 7.2. Overall financial impact of human resources

| Type of human resources | Amount (€) | Method of calculation * |
|---|---|---|
| Officials<br>Temporary staff | | |
| Other human resources<br>(specify budget line) | | |
| Total | | |

The amounts are total expenditure for twelve months.

### 7.3. Other administrative expenditure deriving from the action

| Budget line<br>(number and heading) | Amount € | Method of calculation |
|---|---|---|
| **Overall allocation (Title A7)**<br>A0701 – Missions<br>A07030 – Meetings<br>A07031 – Compulsory committees [1]<br>A07032 – Non-compulsory committees [1]<br>A07040 – Conferences<br>A0705 – Studies and consultations<br>Other expenditure (specify) | | |
| **Information systems (A-5001/A-4300)** | | |
| **Other expenditure - Part A** (specify) | | |
| Total | | |

The amounts are total expenditure for twelve months.

[1] Specify the type of committee and the group to which it belongs.

| | | |
|---|---|---|
| I. | Annual total (7.2 + 7.3) | € |
| II. | Duration of action | years |
| III. | Total cost of action (I x II) | € |

*(In the estimate of human and administrative resources required for the action, DGs/Services must take into account the decisions taken by the Commission in its orientation/APS debate and when adopting the preliminary draft budget (PDB). This means that DGs must show that human resources can be covered by the indicative pre-allocation made when the PDB was adopted.*

*Exceptional cases (i.e. those where the action concerned could not be foreseen when the PDB was being prepared) will have to be referred to the Commission for a decision on whether and how (by means of an amendment of the indicative pre-allocation, an ad hoc redeployment exercise, a supplementary/amending budget or a letter of amendment to the draft budget) implementation of the proposed action can be accommodated.)*

## 8. FOLLOW-UP AND EVALUATION

### 8.1. Follow-up arrangements

Most of the effects of the proposal lend themselves to direct, quantitative measurement. Furthermore, Articles 67 to 70 of Regulation (EC) No 726/2004 lay down financial provisions for the annual preparation, execution, monitoring and reporting of the EMEA budget, including revenues from fees paid by undertakings. Consequently, adequate monitoring data (such as the set of indicators listed in Section 5.3) will be collected in the context of the implementation of these Articles.

### 8.2. Arrangements and schedule for the planned evaluation

It is foreseen that within five years of the entry into force of the Regulation, the Commission will present a report on its implementation. Future reviews will be based on an evaluation of the Agency's costs and on the basis of the related costs of the services provided for by the Member States, and calculated in accordance with generally accepted international costing methods.

Besides, the Agency will provide annually an extensive analysis of the application of this Regulation, through its Annual Report.

## 9. ANTI-FRAUD MEASURES

The European Medicines Agency has specific budgetary control mechanisms and procedures. The Management Board, which comprises representatives of the Member States, the Commission and the European Parliament, adopts the budget (Article 66(f) of Regulation (EC) No 726/2004), as well as the internal financial provisions (Article 66(g)). The European Court of Auditors examines the execution of the budget each year (Article 68.3).

Regarding fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) apply to the EMEA without restriction. Besides, a decision concerning co-operation with the OLAF was already adopted on 1 June 1999 (EMEA/D/15007/99).

Finally, the Quality Management System applied by the Agency supports a continuous review, whose objective is to ensure that the correct procedures are followed and that these procedures and policies are pertinent and efficient. Several internal audits are undertaken each year as part of this process.

## 10. ANNEX: DETAILED CALCULATION OF THE PROPOSAL's FINANCIAL IMPACT

The Commission's proposal aims at amending the current legal framework on the fees payable to the EMEA, as laid down in Council Regulation (EC) No 297/95, as amended, in order to take into account the new tasks of the Agency, as well as the modifications of existing tasks introduced by the recent revision of the pharmaceutical legislation.

As laid down in Article 67(3) of Regulation (EC) No 726/2004, the Agency's revenues consist of a contribution from the Community, and fees paid by companies. As this proposal introduces new fees, it is necessary to assess the quantitative impact of this new scheme, in order to further determine whether or not it would imply a reconsideration of the Community contribution.

**Methodology**

*Nota Bene: Evidently, the financial impact of Regulation (EC) No 726/2004 as such lies outside the scope of this Financial Legislative Statement, since it was already addressed in the context of the global revision of the pharmaceutical legislation*[26].

The Commission's proposal introduces, for a limited subset of fee types, changes (either increases or decreases) in amounts payable to the EMEA (see Table 1).

For these fees where changes are introduced, the numbers of corresponding applications have been estimated, in collaboration with the EMEA, for the 2006-2010 time period[27]. This enables to forecast the financial impact of the fees changes over that period, and to compare it to the Agency's total revenues forecast, as provided by the EMEA[28].

**Results**

The results are given in Tables 2-4. For ease of reference and comparison, the estimates for year 2004 are also provided.

The forecast shows that the overall impact of the fees changes:

-represents 2.8 to 3% of the Agency's annual revenues from fees;

-represents 1.9 to 2.5% of the Agency's total annual revenues (fees + Community contribution);

Given that the error margin for the revenues forecasts is about 5-10%, and that the calculation does not take into account inflation, which at present is around 2.1% in the EU, the overall impact of the fees changes, compared to the Agency's total revenues, is relatively moderate (less than 2.5%).

However, in absolute numbers, this still represents 2 to 4 millions Euros per year and 9% to 15% of the general subsidy entered in budget 2005, which cannot be considered entirely negligible. This should therefore be taken into account in the next budgetary procedures, when reviewing the Community contribution to the EMEA for the 2005-2010 time period. For that review, the 'fees' parameter will also have to be balanced with the costs incurred by the Agency for the implementation of Regulation (EC) No 726/2004.

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26 For more details, see 2001/0252 (COD)

27 As the new Regulation will apply from 20 November 2005, the impact for 2005 is assumed to be negligible.

28 For more details on revenues forecasts, see the '*Report to the European Commission on financing of the EMEA*', Management Board of the EMEA, March 2004.

**Table 1: EMEA Fees changes introduced by the Commission's proposal. Changes are highlighted in bold (4th column)**

| *(in Euros)* | | Current | | Proposal | Dif. | Ref. |
|---|---|---|---|---|---|---|
| **Human** | | | | | | |
| **Full fee** | base | 232000 | | 232000 | 0% | Art. 3(1)(a) |
| | addit. strength/form | 23200 | | 23200 | 0% | Art. 3(1)(a) |
| | addit. presentation | 5800 | | 5800 | 0% | Art. 3(1)(a) |
| **Reduced fee** | base | 116000 | generic | 90000 | **-22%** | Art. 3(1)(b) |
| | | | bio-similar | 150000 | **NEW** | Art. 3(1)(b) |
| | addit. strength/form | 23200 | | 9000 | **-61%** | Art. 3(1)(b) |
| | addit. presentation | 5800 | | 5800 | 0% | Art. 3(1)(b) |
| | | | | | | |
| **Extension fee** | new strength/form etc. | 58000 | max | 69600 | **20%** | Art. 3(1)(c) |
| | new presentation | 11600 | | 5800 | **-50%** | Art. 3(1)(c) |
| **Type I variation** | | 5800 | IA | 2500 | **-57%** | Art. 3(2)(a) |
| | | | IB | 5800 | 0% | Art. 3(2)(a) |
| **Type II variation** | | 69600 | max | 69600 | 0% | Art. 3(2)(b) |
| | | | | | | |
| **Renewal** | | 11600 | | 11600 | 0% | Art. 3(3) |
| **Inspection** | | 17400 | max | 17400 | 0% | Art. 3(4) |
| **Transfer** | | 5800 | | 5800 | 0% | Art. 3(5) |
| **Annual fee** | | 75600 | max | 83200 | **10%** | Art. 3(6) |
| **Referral** | | 58000 | | 58000 | 0% | Art. 4 |
| | | | | | | |
| **Scientific advice** | | 69600 | max | 69600 | 0% | Art. 8(1) |
| **Scientific services** | | | max | 232000 | **NEW** | Art. 8(2) |
| **Administrative services** | | 5800 | max | 5800 | 0% | Art. 8(3) |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Veterinary** | | | | | | |
| **Full fee** | base | 116000 | | 116000 | 0% | Art. 5(1)(a) |
| | addit. strength/form | 11600 | | 11600 | 0% | Art. 5(1)(a) |
| | addit. presentation | 5800 | | 5800 | 0% | Art. 5(1)(a) |
| **Full fee vaccines** | vaccines | 58000 | immunologicals | 58000 | 0% | Art. 5(1)(a) |
| | addit. strength/form/pres. | 5800 | | 5800 | 0% | Art. 5(1)(a) |
| **Reduced fee** | base | 58000 | generic | 58000 | 0% | Art. 5(1)(b) |
| | | | bio-similar | 98000 | **NEW** | Art. 5(1)(b) |
| | addit. strength/form | 11600 | | 11600 | 0% | Art. 5(1)(b) |
| | addit. presentation | 5800 | | 5800 | 0% | Art. 5(1)(b) |
| **Reduced fee vaccines** | vaccines | 29000 | immunologicals | 29000 | 0% | Art. 5(1)(b) |
| | addit. strength/form/pres. | 5800 | | 5800 | 0% | Art. 5(1)(b) |
| | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Extension fee** | new strength/form etc. | 29000 | max | 29000 | 0% | Art. 5(1)c |
| | new presentation | 5800 | | 5800 | 0% | Art. 5(1)c |
| | vaccines | 5800 | (vaccines | 5800 | 0% | Art. 5(1)c |
| **Type I variation** | | 5800 | IA | 2500 | **-57%** | Art. 5(2)(a) |
| | | | IB | 5800 | 0% | Art. 5(2)(a) |
| **Type II variation** | | 34800 | max | 34800 | 0% | Art. 5(2)(b) |
| | vaccines | 5800 | | 5800 | 0% | Art. 5(2)(b) |
| | | | | | | |
| **Renewal** | | 5800 | | 5800 | 0% | Art. 5(3) |
| **Inspection** | | 17400 | max | 17400 | 0% | Art. 5(4) |
| **Transfer** | | 5800 | | 5800 | 0% | Art. 5(5) |
| **Annual fee** | | 25200 | max | 27700 | **10%** | Art. 5(6) |
| **Referral** | | 34800 | | 34800 | 0% | Art. 6 |
| **MRL fee** | base | 58000 | | 58000 | 0% | Art. 7 |
| | amend/extend existing MRL | 17400 | | 17400 | 0% | Art. 7 |
| | clinical trials | 17400 | | 17400 | 0% | Art. 7 |
| | | | | | | |
| **Scientific Advice** | | 34800 | max | 34800 | 0% | Art. 8(1) |
| **Scientific services** | | | max | 116000 | **NEW** | Art. 8(2) |
| **Administrative services** | | 5800 | max | 5800 | 0% | Art. 8(3) |

| | | | | | *2004* | *2005* | **2006** | |
|---|---|---|---|---|---|---|---|---|
| ***Human*** | | ***Current*** | ***Proposal*** | ***Dif.*** | ***# files*** | ***# files*** | ***# files*** | ***financial impact*** |
| **Reduced fee** | generic | 116000 | 90000 | **-26000** | *0* | *0* | 3 | **-78000** |
| | biosimilar | - | 150000 | **150000** | - | - | 3 | **450000** |
| | addit. strength/form | 23200 | 9000 | **-14200** | *0* | *0* | 0 | **0** |
| | | | | | | | | |
| **Extension fee** | new strength/form etc. | 58000 | 69600 | **11600** | *8* | *10* | 10 | **116000** |
| | new presentation | 11600 | 5800 | **-5800** | *4* | *5* | 5 | **-29000** |
| **Type I variation** | Type IA | 5800 | 2500 | **-3300** | *280* | *300* | 330 | **-1089000** |
| **Annual fee** | | 75600 | 83200 | **7600** | *214* | *241* | 264 | **2006400** |
| **Scientific services** | Maximum | - | 232000 | | | | | |
| | VAMF/PMF | - | 30000 | **30000** | - | - | 15 | **450000** |
| | Other | - | 150000 | **150000** | - | - | 3 | **450000** |
| | | | | | | | | |
| **Veterinary** | | | | | | | | |
| **Reduced fee** | biosimilar | - | 98000 | **98000** | - | - | 0 | **0** |
| **Type I variation** | Type IA | 5800 | 2500 | **-3300** | *25* | *30* | 35 | **-115500** |
| **Annual fee** | | 25200 | 27700 | **2500** | *35* | *38* | 42 | **105000** |
| **Scientific services** | | - | 116000 | **116000** | - | - | 0 | **0** |
| | | | | | | | | |
| **Total Impact** | | | | | | | | **2265900** |
| **Total EMEA Revenues from fees** | | | | | *64800000* | *73700000* | | **80397000** |
| ***RELATIVE IMPACT (%)*** | | | | | | | | ***2,8%*** |
| **Total EMEA Revenue (fees+Community contribution)** | | | | | *96619000* | *108237000* | | **117615000** |
| ***RELATIVE IMPACT (%)*** | | | | | | | | ***1,9%*** |

**Table 2: Financial impact of the proposal for 2005-2006. Financial figures are given in Euros. Estimates for year 2004 are also provided, for information. As the new Regulation will apply from 20 November 2005, the impact for 2005 is assumed to be negligible.**

**Note: Regarding Scientific services for medicinal products for human use, the Commission's proposal introduces a wide range of fees amounts (from 2500 Euros to 232 000 Euros), depending on the type of service actually provided. The calculation is based on the assumption that the fees for certification of Vaccine Antigen Master Files and Plasma Master Files (VAMF/PMF) will be about 30000 Euros, and that other services will be charged 150000 Euros on average.**

| | | | | | 2007 | | 2008 | |
|---|---|---|---|---|---|---|---|---|
| ***Human*** | | ***Current*** | ***Proposal*** | ***Dif.*** | ***# files*** | ***financial impact*** | ***# files*** | ***financial impact*** |
| **Reduced fee** | generic | 116000 | 90000 | **-26000** | 6 | **-156000** | 8 | **-208000** |
| | biosimilar | - | 150000 | **150000** | 5 | **750000** | 6 | **900000** |
| | addit. strength/form | 23200 | 9000 | **-14200** | 1 | **-14200** | 1 | **-14200** |
| | | | | | | | | |
| **Extension fee** | new strength/form etc. | 58000 | 69600 | **11600** | 12 | **139200** | 14 | **162400** |
| | new presentation | 11600 | 5800 | **-5800** | 6 | **-34800** | 7 | **-40600** |
| **Type I variation** | Type IA | 5800 | 2500 | **-3300** | 355 | **-1171500** | 380 | **-1254000** |
| **Annual fee** | | 75600 | 83200 | **7600** | 280 | **2128000** | 307 | **2333200** |
| **Scientific services** | Maximum | - | 232000 | | | | | |
| | VAMF/PMF | - | 30000 | **30000** | 20 | **600000** | 18 | **540000** |
| | Other | - | 150000 | **150000** | 5 | **750000** | 5 | **750000** |
| | | | | | | | | |
| **Veterinary** | | | | | | | | |
| **Reduced fee** | biosimilar | - | 98000 | **98000** | 0 | **0** | 0 | **0** |
| **Type I variation** | Type IA | 5800 | 2500 | **-3300** | 40 | **-132000** | 46 | **-151800** |
| **Annual fee** | | 25200 | 27700 | **2500** | 47 | **117500** | 53 | **132500** |
| **Scientific services** | | - | 116000 | **116000** | 0 | **0** | 0 | **0** |
| | | | | | | | | |
| **Total Impact** | | | | | | **2976200** | | **3149500** |
| **Total EMEA Revenues from fees** | | | | | | **90416000** | | **99518000** |
| ***RELATIVE IMPACT (%)*** | | | | | | ***3,3%*** | | ***3,2%*** |
| **Total EMEA Revenue (fees+Community contribution)** | | | | | | **128567000** | | **138446000** |
| ***RELATIVE IMPACT (%)*** | | | | | | ***2,3%*** | | ***2,3%*** |

**Table 3: Financial impact of the proposal for 2007-2008. Financial figures are given in Euros.**

| | | | | | 2009 | | 2010 | |
|---|---|---|---|---|---|---|---|---|
| ***Human*** | | ***Current*** | ***Proposal*** | ***Dif.*** | ***# files*** | ***financial impact*** | ***# files*** | ***financial impact*** |
| **Reduced fee** | generic | 116000 | 90000 | **-26000** | 10 | **-260000** | 12 | **-312000** |
| | biosimilar | - | 150000 | **150000** | 6 | **900000** | 7 | **1050000** |
| | addit. strength/form | 23200 | 9000 | **-14200** | 2 | **-28400** | 3 | **-42600** |
| | | | | | | | | |
| **Extension fee** | new strength/form etc. | 58000 | 69600 | **11600** | 17 | **197200** | 19 | **220400** |
| | new presentation | 11600 | 5800 | **-5800** | 8 | **-46400** | 9 | **-52200** |
| **Type I variation** | Type IA | 5800 | 2500 | **-3300** | 410 | **-1353000** | 450 | **-1485000** |
| **Annual fee** | | 75600 | 83200 | **7600** | 335 | **2546000** | 360 | **2736000** |
| **Scientific services** | Maximum | - | 232000 | | | | | |
| | VAMF/PMF | - | 30000 | **30000** | 20 | **600000** | 19 | **570000** |
| | Other | - | 150000 | **150000** | 7 | **1050000** | 8 | **1200000** |
| | | | | | | | | |
| **Veterinary** | | | | | | | | |
| **Reduced fee** | biosimilar | - | 98000 | **98000** | 1 | **98000** | 1 | **98000** |
| **Type I variation** | Type IA | 5800 | 2500 | **-3300** | 50 | **-165000** | 58 | **-191400** |
| **Annual fee** | | 25200 | 27700 | **2500** | 57 | **142500** | 62 | **155000** |
| **Scientific services** | | - | 116000 | **116000** | 0 | **0** | 0 | **0** |
| | | | | | | | | |
| **Total Impact** | | | | | | **3680900** | | **3946200** |
| **Total EMEA Revenues from fees** | | | | | | **110780000** | | **121455000** |
| ***RELATIVE IMPACT (%)*** | | | | | | ***3,3%*** | | ***3,2%*** |
| **Total EMEA Revenue (fees+Community contribution)** | | | | | | **149493000** | | **161145000** |
| ***RELATIVE IMPACT (%)*** | | | | | | ***2,5%*** | | ***2,4%*** |

**Table 4: Financial impact of the proposal for 2009-2010. Financial figures are given in Euros.**