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COMMISSION STAFF WORKING PAPER

Annex to the **:**

Proposal for a Council Regulation amending Regulation (EC) No 297/95 on fees payable to the European Medicines Agency

IMPACT ASSESSMENT

{COM(2005) 106 final}

TITLE OF PROPOSAL

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

DOCUMENT REFERENCE NUMBER – COM(2005)106 FINAL

WHAT ISSUE IS THE PROPOSAL EXPECTED TO TACKLE?

The EU pharmaceutical legislation has recently been revised[1]. In this context, news tasks and responsibilities have been conferred to the European Medicines Agency (EMEA, "the Agency"). Already existing tasks have also been revised. It is therefore necessary to amend the current legal framework on the fees payable to the EMEA, as laid down in Council Regulation (EC) No 297/95[2], so as to reflect these modifications. Without such a revision, the existing fee scheme would not be sufficient to appropriately cover the costs incurred by the EMEA in the context of the 'new' pharmaceutical legislation.

The two main parties affected are (i) the industry, *i.e.* applicants requesting the scientific services of the EMEA, and (ii) the Agency itself, whose revenues are directly dependent on the fees amounts.

WHAT MAIN OBJECTIVE IS THE PROPOSAL EXPECTED TO REACH?

Three major objectives are pursued:

- To adapt the existing fee scheme to the revised pharmaceutical 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.

The proposal's objectives are in line with 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.*:

(1) Protecting public health across the Community;

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1 See in particular Regulation (EC) No 726/2004, OJ L 136, 30.4.2004, p. 1.

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

(3) Supporting the achievement of the internal market for the pharmaceutical sector.

WHAT ARE THE MAIN POLICY OPTIONS AVAILABLE TO REACH THE OBJECTIVE?

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.

Within this framework, the main policy options are:

- To increase/decrease the levels of existing fees;
- To create new categories of fees;
- To extend/reduce the flexibility conferred to the Management Board and to the Executive Director of the EMEA to adapt certain fees, under certain conditions, to the particular situation of the application and the related product.

Evidently, these options are not mutually exclusive.

WHAT ARE THE IMPACTS EXPECTED FROM THE DIFFERENT OPTIONS IDENTIFIED?

To evaluate the impact of the different policy options, two analyses have been carried out: a retrospective analysis of the operation of the existing fee scheme; and a prospective analysis of the anticipated impact of the revised pharmaceutical legislation[3].

In particular, the EMEA has provided the Commission with an in-depth assessment of the operation of the current system[4]. This 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 fulfill its mission since its creation in 1995; they should therefore be maintained. Thus, most of the fees should not be changed. Consequently, it is expected that the overall financial impact of the proposal will be rather minimal. This is further confirmed by the detailed financial analysis provided in the Legislative Financial Statement.

Only a few fees changes have been introduced in the proposal. One of them relates to a 10% increase of the annual fee, both for medicinal products for human use and veterinary medicinal products. Such option has been chosen based on the fact that costs related to post-authorisation activities are, at present, not adequately covered by the corresponding annual

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[3] For more details on these two analyses, see the Explanatory Memorandum

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

fee, and that the EMEA revenues depend too heavily on the payment of initial fees related to new applications, which affects the long-term financial stability of the Agency. As far as the EMEA is concerned, this fee increase should thus have a positive impact, by stabilising the Agency's revenue stream and strengthening its capacity to perform long-term, multi-annual tasks.

From the industry viewpoint, the impact is less easy to predict. However, it should be noted that the proposed level of the annual fee (83200 Euros for medicinal products for human use, 27700 Euros for veterinary medicinal products) is relatively low compared to the typical annual turnover for a medicinal product authorised through the centralised procedure. In addition, this level is a maximum: as specified in the proposal, a reduced annual fee will apply for certain types of medicinal products. As a result, it can be expected that the impact of this fee increase will be moderate.

The proposal also introduces a decreased fee for applications for generic medicinal products, as well as a new fee category for similar biological medicinal products. This should facilitate the submission of these products through the centralised procedure, without any detrimental impact on the EMEA revenues. In any case, the payment of the application fee is clearly not the financial rate-limiting step for the development, authorisation and marketing of these types of medicines.

Note: As detailed in this section and in the Legislative Financial Statement, the overall financial impact of the proposal is considered to be minimal. However, particular attention should be paid to small and medium-sized enterprises (SMEs), which may be more easily affected by these fees changes than bigger pharmaceutical companies. In that respect, Article 70(2) of Regulation (EC) No 726/2004 foresees that provisions shall be adopted by the Commission, establishing the circumstances in which SMEs may pay reduced fees, defer payment of the fee, or receive administrative assistance. Thus, the specific situation of SMEs has to be considered separately, i.e. outside the scope of this proposal.

HOW TO MONITOR AND EVALUATE THE RESULTS AND IMPACTS OF THE PROPOSAL AFTER IMPLEMENTATION?

The proposal primarily deals with the fee-dependant revenues side of the EMEA's budget. To monitor this, the EMEA 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).

In addition, it is foreseen that within five years of the entry into force of the proposed 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.

STAKEHOLDER CONSULTATION

As laid down in Article 70(1) of Regulation (EC) No 726/2004, the Commission's proposal must be submitted once organisations representing the interests of the pharmaceutical industry have been consulted at Community level.

In July-September 2004, the European Commission held an external consultation on its draft proposal for a Council Regulation on the fees payable to the European Medicines Agency. Contributions were received from industry associations, regulators, and individual companies (a full listing of all respondents is provided at the end of this section). 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 Commission's draft 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 service, and the related costs, was strongly emphasised.

In the light of the abovementioned principle, some respondents challenged the rationale for proposing a 10% increase of the annual fee. The main argument was that, as laid down in Article 67(4) of Regulation (EC) No 726/2004, activities relating to pharmacovigilance, to the operation of communications networks and to market surveillance shall receive adequate public funding commensurate with the tasks conferred, and hence can only be subject to partial and limited fee funding. However, such funding alone may not be sufficient to fully cover other post-authorisation administrative costs, e.g. maintaining up-to-date marketing authorisation dossiers and the various databases managed by the Agency. Besides, public funding would not be sufficient to reduce the Agency's financial dependence on new applications.

In the field of generics and similar biological medicinal products, the relevant stakeholders welcomed the introduction of a specific fee for 'bio-similars', as well as the substantial decrease of the fee for a generic marketing authorisation application.

Regarding veterinary medicinal products, the main industrial stakeholder expressed concern over certain fee increases which were initially put forward in the proposal. Taking into account these comments, the fact that the centralised procedure is mandatory for a limited subset of veterinary medicinal products only[5], and the specific nature of the animal health market, it was subsequently decided to withdraw the referred fee increases, and to keep the vast majority of the fees for veterinary medicinal products to the same level.

Lastly, respondents welcomed the introduction of new concepts, such as 'scientific services', to address the new tasks performed by the Agency in the context of the revised pharmaceutical legislation. Some contributions provided useful feedback for the development of detailed lists of fees, which indeed could greatly differ depending on the actual service provided.

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[5] Medicinal products for veterinary use intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals, see Annex of Reg. (EC) No 726/2004.

LIST OF RESPONDENTS

- Dutch Ministry of Health, Welfare and Sport (Director of the Department of Pharmaceutical Affairs and Medical Technology)
- AESGP (Association of the European Self-medication Industry)
- IFAH-Europe (representing the European Animal Health Industry)
- EFPIA (European Federation of Pharmaceutical Industries and Associations)
- EGA (European Generic medicines Association)
- EPFA (European Plasma Fractionation Association)
- EuropaBio/BIA/EBE (European Association for BioIndustries, BioIndustry Association, Emerging Biopharmaceutical Enterprises)
- MSD Europe (affiliate of Merck & Co., Inc. (USA))

COMMISSION DRAFT PROPOSAL AND JUSTIFICATION

See the Explanatory Memorandum and the Proposal.