Fees payable to the European Medicines Agency

2005/0023(CNS) - 31/03/2005 - Document attached to the procedure

COMMISSION'S IMPACT ASSESSMENT

For further information regarding the context of this issue, please refer to the summary of the Commission's initial proposal COM(2005)0106 concerning the amendment of Regulation 297/95/EC on fees payable to the European Medicines Agency.

1- POLICY OPTIONS AND IMPACTS

1.1-Option 1 - To increase/decrease the levels of existing fees.

1.2-Option 2 - To create new categories of fees;

1.3-Option 3 - 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.

IMPACTS

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.

Retrospective analysis:the EMEA has provided the Commission with an in-depth assessment of the operation of the current system. 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 fulfil 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.

Prospective analysis: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 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 (EUR 83 200 for medicinal products for human use, EUR 27 700 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 reduced 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's 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.

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 726 /2004/EC 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.

*CONCLUSION:***the options identified by the Commission are not mutually exclusive.**

2- FOLLOW-UP

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 726/2004/EC), 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.

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