

Fees payable to the European Medicines Agency

2005/0023(CNS) - 31/03/2005 - Legislative proposal

PURPOSE : to amend some of the rules regarding fees payable to the European Medicines Agency and to amend Regulation 297/95/EC.

PROPOSED ACT : Council Regulation.

CONTENT : the pharmaceutical legislation has recently been revised and in this context Regulation 726/2004/EC established a European Medicines Agency. The Agency's revenue consists 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 fee scheme, as laid down in Council Regulation 297/95/EC on fees payable to the EMEA, 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.

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.

FINANCIAL IMPLICATIONS :

Budget lines and headings : 02.040201 and 02.040202.

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 726/2004/EC 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 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.