Basic information

2005/0023(CNS) CNS - Consultation procedure Regulation	Procedure completed
Fees payable to the European Medicines Agency Amending Regulation (EC) No 297/95 1994/0220(CNS) **Subject** 4.20.04 Pharmaceutical products and industry 8.40.08 Agencies and bodies of the EU	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	FLORENZ Karl-Heinz (PPE-DE)	24/05/2005

Committee for opinion	Rapporteur for opinion	Appointed
BUDG Budgets	The committee decided not to give an opinion.	09/06/2005

Council of the European Union

Council configuration	Meetings	Date
Education, Youth, Culture and Sport	2689	2005-11-14

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	

Key events

Date	Event	Reference	Summary
31/03/2005	Legislative proposal published	COM(2005)0106	Summary
26/05/2005	Committee referral announced in Parliament		
14/09/2005	Vote in committee		Summary
16/09/2005	Committee report tabled for plenary, 1st reading/single reading	A6-0264/2005	
27/09/2005	Decision by Parliament	T6-0345/2005	Summary

27/09/2005	Results of vote in Parliament		
14/11/2005	Act adopted by Council after consultation of Parliament		
14/11/2005	End of procedure in Parliament		
23/11/2005	Final act published in Official Journal		

Technical information

Procedure reference	2005/0023(CNS)
Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Amending Regulation (EC) No 297/95 1994/0220(CNS)
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/27454

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A6-0264/2005	16/09/2005	
Text adopted by Parliament, 1st reading/single reading		T6-0345/2005 OJ C 227 21.09.2006, p. 0018-0040 E	27/09/2005	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2005)0106	31/03/2005	Summary
Document attached to the procedure	SEC(2005)0407	31/03/2005	Summary
Commission response to text adopted in plenary	SP(2005)4139	20/10/2005	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Regulation 2005/1905
OJ L 304 23.11.2005, p. 0001-0009 Summary

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.

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.

Fees payable to the European Medicines Agency

2005/0023(CNS) - 14/11/2005 - Final act

PURPOSE: To amend Regulation 297/95 on fees payable to the European Medicines Agency.

LEGISLATIVE ACT: Council Regulation 1905/2005 amending Regulation 297/95 on fees payable to the European Medicines Agency.

CONTENT: The amendments to Regulation 297/95 establish new rules for the registration of medicines for human and veterinary use at the European Medicines Agency (EMEA). Under the terms of the new Regulation, a number of fees will be reduced whilst the principles of proportionality will be reinforced. The newly adopted rules include:

- A number of fee reductions, for example, for the evaluation of generic products or where minor changes, (variations), in the marketing authorisation dossiers have taken place.
- New fee categories for new services provided by the EMEA such as scientific opinions on traditional herbal medicines.
- Room for flexibility to allow for the adoption of certain fees to the type of service being provided.
- Increasing the maximum threshold for the annual fee by 10%, while giving a mandate to the EMEA Management Board to define cases where a reduced annual fee should apply.

The amended Regulation lists the exact amounts to be paid for the services provided and is divided into the following headings:

- Medicinal products for human use covered by Regulation 726/2004.
- Medicinal products for human use covered by Directive 2001/83/EC.
- Medicinal products for veterinary use covered by Regulation 726/2004.
- Veterinary medicinal products covered by Directive 2001/82/EC.
- Establishment of maximum residue limits for veterinary medicinal products according to Regulation 2377/90.
- Various fees (for scientific advice etc).

The Commission will review all fees in accordance with inflation every April with any updates being published in the Official Journals. A separate Regulation on financial and administrative incentives for SME's is currently being prepared by the Commission. The Regulation applies from 20 November 2005, which coincides with the full entering into force of Regulation 726/2004. Valid applications pending on 20 November 2005 will not be covered by the provisions in this Regulation.

ENTRY INTO FORCE: 24 November 2005.

Fees payable to the European Medicines Agency

2005/0023(CNS) - 27/09/2005 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Karl-Heinz **FLORENZ** (EPP-ED, DE) Approving the proposal, subject to a few amendments. (Please see the document dated 14/09/2005.) The amendments were as follows:

-In order to respect the principle of proportionality, medicinal products in which the active substances have been in well-established medicinal use within the Community for at least ten years should benefit from a reduced annual fee.

-In exceptional cases, where an extensive workload relating to the evaluation of an application for marketing authorisation pursuant to Article 10a of Directive 2001/83/EC can be demonstrated, a fee of up to EUR 232 000 may be determined.

-When it concerns the evaluation of traditional herbal medicinal products, the fee will be not more than EUR 25 000.

-A reduced scientific service fee falling within the range of EUR 2 500 to EUR 25 000 shall apply for certain scientific opinions or services concerning traditional herbal medicinal products.