Procedure file

Basic information

CNS - Consultation procedure Regulation	1998/0135(CNS)	Procedure completed
Fees payable to the European Agency for the Evaluation of Medicinal Products 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
	BUDG Budgets	PSE TAPPIN Michael	03/06/1998
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Consumer Protection	PPE VALVERDE LÓPEZ José	02/06/1998
	CONT Budgetary Control	PPE KELLETT-BOWMAN Edward T.	29/06/1998
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	2151	14/12/1998
	Competitiveness (Internal Market, Industry, Research and Space)	2130	09/11/1998

Key events

21/01/1998	Legislative proposal published	COM(1998)0021	Summary
27/05/1998	Committee referral announced in Parliament		
22/09/1998	Vote in committee		
22/09/1998	Committee report tabled for plenary, 1st reading/single reading	A4-0338/1998	
06/10/1998	Debate in Parliament		
07/10/1998	Decision by Parliament	T4-0557/1998	Summary
11/11/1998	Modified legislative proposal published	COM(1998)0648	Summary

14/12/1998	Act adopted by Council after consultation of Parliament		
14/12/1998	End of procedure in Parliament		
19/12/1998	Final act published in Official Journal		

Technical information

Procedure reference	1998/0135(CNS)
Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation (EC) No 297/95 1994/0220(CNS)
Legal basis	EC before Amsterdam E 000
Stage reached in procedure	Procedure completed
Committee dossier	BUDG/4/10088

Documentation gateway

Legislative proposal		COM(1998)0021 OJ C 022 27.01.1999, p. 0011	21/01/1998	EC	Summary
Committee report tabled for plenary, 1st reading/single reading		A4-0338/1998 OJ C 328 26.10.1998, p. 0004	22/09/1998	EP	
Text adopted by Parliament, 1st reading/single reading		T4-0557/1998 OJ C 328 26.10.1998, p. 0073-0094	07/10/1998	EP	Summary
Modified legislative proposal		COM(1998)0648 OJ C 036 10.02.1999, p. 0017	11/11/1998	EC	Summary

Additional information

European Commission	EUR-Lex

Final act

Regulation 1998/2743
OJ L 345 19.12.1998, p. 0003 Summary

Fees payable to the European Agency for the Evaluation of Medicinal Products

OBJECTIVE: to amend Regulation (EC) No 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products (EMEA). SUBSTANCE: in the light of experience since 1995, it is deemed appropriate to retain the general principles and overall structure of the fee system, as well as the main operational and procedural provisions laid down by Regulation (EC) No 297/95. However, in the case of certain fees, the proposal seeks to define more precisely the services to which they relate in order to facilitate their recovery and improve the transparency and practical implementation of the Regulation. The Commission proposal includes three new initiatives: - the possibility for the EMEA Management Board, on a proposal by the Executive Director, to determine those cases in which the fee payable for a variation of major importance (type II) may be halved; - the introduction of an annual fee to cover costs of supervision of medicinal products whose marketing has been authorised by the Community and the maintenance of these authorisations; - the introduction of a fee for scientific advice and protocol assistance given to future applicants in the design of their research and development programmes. The proposed new provisions also include initiatives for a fee for the establishment of maximum residue limits for clinical trials, administrative charges and the introduction of differentiated fees for the initiation of Community referral procedures under Directives 75/319/EEC and 81/851/EEC. ?

Fees payable to the European Agency for the Evaluation of Medicinal Products

In adopting the report by Mr Michael TAPPIN (PSE, UK) on the European Agency for the Evaluation of Medicinal Products, the European Parliament adopted a number of amendments to render more stringent the obligation to consult Parliament about the fees payable to the Agency. The general principle of own resources is recalled, and the link between the Agency's resources and the EU budget is confirmed (Parliament particularly stresses that the fees charged by the Agency must be regarded as Community revenue and entered in the budget as preallocated resources for the Agency). Parliament seeks to give the Agency the flexibility it needs as regards the granting of EU funds. ?

Fees payable to the European Agency for the Evaluation of Medicinal Products

The Commission accepts, in part or in full, those of the European Parliament's amendments covering the following areas: - if the fee is increased on initiation of the arbitration procedure in respect of a marketing authorisation for a veterinary medicinal product, such an increase is to remain pegged within a ceiling of ECU 20,000 ; - any increase in the additional fee for an application to amend or extend an existing MLR is to remain pegged within a ceiling of ECU 15,000 ; - introduction of the principle of maximum fees for applications for scientific advice ; - future reviews of fees shall be based on a full cost evaluation of the costs of the Agency, including expenditure relating to Member States' rapporteurs. The Commission rejects those amendments covering the following areas: - a change in the legal basis of the proposed text, as the derived legal basis is perfectly appropriate ; - the budget rules applicable to the Agency, as this does not specifically concern the levels and structure of the fees payable to the Agency for the evaluation of medicinal products and these aspects are in any case subject to a draft horizontal regulation covering all agencies under discussion; - the replacement of the ecu with the euro, as this will need to be covered by a horizontal text covering all Community texts ; - the reintroduction of ceilings for fees directly linked to the granting of marketing authorisations under the centralised procedure as this cannot be justified either in terms of the service provided by the Agency or on public health grounds and the principles governing the rational use of medicinal products preclude the proliferation of different pharmaceutical forms of the same medicinal product.?

Fees payable to the European Agency for the Evaluation of Medicinal Products

OBJECTIVE: to amend Regulation (EC) no. 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products (EMEA). CONTENTS: the general principles and overall structure of the fee system, as well as the main operational and procedural provisions laid down by Regulation (EC) no. 297/95 have been maintained. However, in the case of certain fees, the Regulation defines the services to which they relate in order to facilitate their recovery and improve the transparency and practical implementation of the basic Regulation. The main amendments introduced by the Council concern: - the possibility for the EMEA management board, on a proposal by the Executive Director and the opinion of the relevant scientific committee, to determine those cases in which the fee may be reduced; - the introduction of an annual fee to cover costs of supervision of medicinal products whose marketing has been authorised by the Community; - the introduction of a fee for scientific advice and protocol assistance given to future applicants in the design of their research and development programmes. The new provisions also introduce a fee for the establishment of maximum residue limits for clinical trials, administrative charges and differentiated fees for the initiation of Community referral procedures under Directives 75/319/EEC and 81/851/EEC. ENTRY INTO FORCE: 20 December 1998.?