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

1998/0135(CNS) - 14/12/1998 - Final act

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.