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

1998/0135(CNS) - 21/01/1998 - Legislative proposal

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.