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

1998/0135(CNS) - 11/11/1998 - Modified legislative proposal

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.