European Agency for the Evaluation of Medicinal Products: fees payable

1994/0220(CNS) - 27/05/1994 - Legislative proposal

From 1995, the European Agency for the Evaluation of Medicinal Products would be called upon to examine requests for authorisation to market medicinal products from pharmaceutical companies, which would result in the collection of fees to provide revenue for the Agency's budget. This proposal for a regulation aimed to lay down the structure and the amount of fees paid by undertakings for the examination and revision of Community authorisations to market medicinal products and other services provided by the Agency. According to the proposal, an undertaking should pay a basic Community fee of ECU 200 000 for medicinal products for human use and ECU 100 000 for veterinary medicinal products with a view to obtaining an authorisation to market the said products as required by the centralised procedure. The proposal also provided for a number of other fees: - a reduced fee for applications which did not have to be supported by a full dossier (ECU 100 000 for products for human use; ECU 50 000 for veterinary products); - an extension fee when the applicant wished to extend the applications made for the same medicinal product (ECU 40 000 for products intended for human use; ECU 20 000 for veterinary products); -a variation fee for minor administrative modifications of type I, which was fixed at ECU 5 000, and a variation fee for complex modifications of type II, which was fixed at ECU 40 000 for medicinal products for human use and at ECU 20 000 for veterinary products; - a renewal fee which was charged for the obligatory five-yearly renewal of the Community marketing authorisation (ECU 40 000 for products for human use; ECU 20 000 for veterinary products); - a flat-rate fee of ECU 10 000 for inspections which were undertaken subsequent to the issuing of a marketing authorisation, at the request of, or in the interest of, its holder; -a fee which was charged for the Agency's arbitration services in the event of disagreement between Member States as to the authorisation of a medicinal product in accordance with the decentralised procedure (ECU 40 000 for medicinal products for human use; ECU 20 000 for veterinary products). In exceptional circumstances - medicinal products treating a limited number of patients with a rare disease, SMEs, imperative reasons of public health - waivers and fee reductions could be granted.