European Agency for the Evaluation of Medicinal Products: fees payable

1994/0220(CNS) - 10/02/1995 - Final act

OBJECTIVE : Council Regulation (EC) No 297/95 lays down the structure and the amount of fees paid by undertakings for the examination and revision of Community authorizations to market medicinal products and other services provided by the European Agency for the Evaluation of Medicinal Products.

SUBSTANCE : Undertakings have to pay a basic Community fee of ECU 140,000 for medicinal products for human use, and ECU 70,000 for veterinary medicinal products, with a view to obtaining an authorization to market the said products as required by the centralized procedure.

The Regulation also provides for a number of other fees as follows:

- a reduced fee for applications which do not have to be supported by a full dossier (ECU 70,000 for products for human use; ECU 35,000 for veterinary products);
- an extension fee when the applicant wishes 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 is fixed at ECU 5,000, and a variation fee for complex modifications of type II, which is fixed at ECU 40,000 for medicinal products for human use and at ECU 20,000 for veterinary products;
- a renewal fee which is charged for the obligatory five-yearly renewal of the Community marketing authorization (ECU 10,000 for products for human use; ECU 5,000 for veterinary products);
- a flat-rate fee of ECU 10,000 for inspections which are undertaken subsequent to the issuing of a marketing authorization, at the request of, or in the interest of, its holder;
- a fee which is charged for the Agency's arbitration services in the event of disagreement between Member States as to the authorization of a medicinal product in accordance with the decentralized procedure (ECU 30,000 for medicinal products for human use; ECU 15,000 for veterinary products). In exceptional circumstances, and for imperative reasons of public or animal health, waivers and fee reductions may be granted on a case by case basis.

The Agency shall indicate in its annual estimate intended for the establishment of the preliminary draft budget of the Commission the estimates concerning revenues obtained from fees for the following financial year.

Date of entry into force of the Regulation: 16.02.1995.