

Fees payable to the European Medicines Agency

2005/0023(CNS) - 14/11/2005 - Final act

PURPOSE: To amend Regulation 297/95 on fees payable to the European Medicines Agency.

LEGISLATIVE ACT: Council Regulation 1905/2005 amending Regulation 297/95 on fees payable to the European Medicines Agency.

CONTENT: The amendments to Regulation 297/95 establish new rules for the registration of medicines for human and veterinary use at the European Medicines Agency (EMA). Under the terms of the new Regulation, a number of fees will be reduced whilst the principles of proportionality will be reinforced. The newly adopted rules include:

- A number of fee reductions, for example, for the evaluation of generic products or where minor changes, (variations), in the marketing authorisation dossiers have taken place.
- New fee categories for new services provided by the EMA such as scientific opinions on traditional herbal medicines.
- Room for flexibility to allow for the adoption of certain fees to the type of service being provided.
- Increasing the maximum threshold for the annual fee by 10%, while giving a mandate to the EMA Management Board to define cases where a reduced annual fee should apply.

The amended Regulation lists the exact amounts to be paid for the services provided and is divided into the following headings:

- Medicinal products for human use covered by Regulation 726/2004.
- Medicinal products for human use covered by Directive 2001/83/EC.
- Medicinal products for veterinary use covered by Regulation 726/2004.
- Veterinary medicinal products covered by Directive 2001/82/EC.
- Establishment of maximum residue limits for veterinary medicinal products according to Regulation 2377/90.
- Various fees (for scientific advice etc).

The Commission will review all fees in accordance with inflation every April with any updates being published in the Official Journals. A separate Regulation on financial and administrative incentives for SME's is currently being prepared by the Commission. The Regulation applies from 20 November 2005, which coincides with the full entering into force of Regulation 726/2004. Valid applications pending on 20 November 2005 will not be covered by the provisions in this Regulation.

ENTRY INTO FORCE: 24 November 2005.