

Fees payable to the European Medicines Agency

2005/0023(CNS) - 27/09/2005 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Karl-Heinz **FLORENZ** (EPP-ED, DE) Approving the proposal, subject to a few amendments. (Please see the document dated 14/09/2005.) The amendments were as follows:

-In order to respect the principle of proportionality, medicinal products in which the active substances have been in well-established medicinal use within the Community for at least ten years should benefit from a reduced annual fee.

-In exceptional cases, where an extensive workload relating to the evaluation of an application for marketing authorisation pursuant to Article 10a of Directive 2001/83/EC can be demonstrated, a fee of up to EUR 232 000 may be determined.

-When it concerns the evaluation of traditional herbal medicinal products, the fee will be not more than EUR 25 000.

-A reduced scientific service fee falling within the range of EUR 2 500 to EUR 25 000 shall apply for certain scientific opinions or services concerning traditional herbal medicinal products.