

Fees payable to the European Medicines Agency

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The committee adopted the report by its chairman, Karl-Heinz FLORENZ (EPP-ED , DE), approving the proposal under the consultation procedure subject to a few amendments aimed at ensuring proportionality and flexibility:

- in line with the principle of proportionality, existing medicinal products whose active substances have been in well-established medicinal use within the Community for at least 10 years should benefit from a reduced annual fee. MEPs argued that the workload related to monitoring such products was significantly lower than in the case of products with a completely new chemical entity. The provisions on the reduced fee applicable to bibliographical applications were amended to reflect this;
- the regulation should leave room for flexibility in the case of scientific services for special medicinal products. As regards traditional herbal medicinal products, the full fee of EUR 232 000 would be totally out of proportion. The committee therefore proposed an evaluation fee of not more than EUR 25 000 and a reduced scientific service fee of between EUR 2 500 and 25 000 for certain scientific opinions or services concerning traditional herbal medicines.