European Agency for the Evaluation of Medicinal Products: fees payable

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The Commission presents a communication aiming to **update the financial statement** accompanying Regulation (EC) n° 297/95 in order to reflect the actual staffing needs of the European Medicines Agency.

The European Medicines Agency was set up by Regulation (EC) No 726/2004 of the European Parliament and of the Council. This Regulation establishes that the revenue of the Agency shall consist of a contribution from the European Union, and the fees paid by the undertaking for obtaining and maintaining a Community marketing authorisation and for other services provided by the Agency.

Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency sets out the different types of fees payable for services provided, including the possibility for waivers and reductions of certain fees. The corresponding financial statements (if applicable) for Regulation (EC) No 297/95 and its amendments in 19984, 20035 and 2005 did not provide for the human resources required to handle fee-related applications.

The Budgetary Authority agreed to additional staff for fee-related activities in 2010. For 2011 and 2012 no additional fee-financed staffing was provided; the additional posts agreed for 2012 correspond to the implementation of the new pharmacovigilance activities only.

In the draft budget for 2013, the Commission agreed on an increase of the Agency's establishment plan with **21 additional posts, to be financed by fees from the industry**. With this Communication, the Commission presents the factors that justify this increase, these being:

- the fee-related activities of EMA have developed substantially since 2010, entailing an expansion of workload for the Agency, yet with no corresponding increase in staff;

- at the same time, the fee-related income of the Agency, based on recovery orders/invoices sent, increased from EUR 171,9 million in 2010 to EUR 179,8 million in 2011 and is estimated to increase further to EUR 200.8 million in 2013. This corresponds to a 5.9% increase for the period 2010-12 and a 16.8% increase over the period 2010-13, which translates into the corresponding increase in workload.

These recent developments in fee-related activities are of a long-term nature and the Agency requires 21 additional temporary agents as of 2013. **The initial financial statement should therefore be revised** to adapt to the reality of the agency's staffing needs. The extra staff will be funded by the fee income generated through these activities and is therefore **neutral for the EU budget.**

The Commission emphasises that the current fee-financed increase in staffing is not linked to the implementation of the new pharmacovigilance legislation, applicable as of July 2012.