

# 2002 discharge: European Agency for the Evaluation of Medicinal Products

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**PURPOSE** : to present the report from the Court of Auditors on the financial statements of the European Agency for the Evaluation of Medicinal Products (EMA) concerning the financial year 2002.

**CONTENT** : this report concerns the results of the audit performed by the Court of the financial statements of the European Agency for the Evaluation of Medicinal Products for the financial year ended 31/12/2002. This examination has enabled the Court to obtain reasonable assurance that the annual accounts are reliable and that the underlying transactions, taken as a whole, are legal and regular. The report highlights that the final appropriations entered for the financial year amount to EUR 61,3 million, committed to the amount EUR 58,4 million with EUR 51,6 million being paid. The total amount carried over was EUR 6,8 million and EUR 2,9 million was cancelled. The amount of outstanding commitments from the previous year amount to EUR 13,5 million of which EUR 12,2 have been paid and EUR 1,3 million has been cancelled. The report states in particular that Agency dedicates a significant part of its budget to the financing of pharmaceutical supervision systems. As soon as the scientific committees decide to carry out an inspection of a medicinal product, a proposal for a commitment is issued in respect of the fee to be paid to the national agency responsible for carrying out the inspection. This procedure does not allow the principle of annuality to be respected, since delays in carrying out the work mean that the expenditure will be settled during a later financial year. In addition, it increases administrative expenditure as a result of cancellations and new commitments. On the issue of financial statements, the report shows that applying principles of accruals accounting, contrary to the current regulations which provide for cash-based accounting, the Agency included in its revenue EUR 5,2 million due in respect of the financial year 2002 (in 2001, EUR 10,7 million had been included in the revenue). The Agency frequently receives lump-sum advances for examinations which the users of its services are considering requesting. It is difficult to reconcile the amounts customers have paid and the fees actually due. The delays affecting the processing of files partly explain the 75 % increase in the amount of advances not allocated at the end of 2002. Concerning the issue of invoices, these are paid after the authorising officer, who certifies that the service has been performed or the goods delivered, has given his approval. This is issued without any systematic provision of supporting documents. The absence of such information, which is necessary in order to carry out efficient internal control, creates uncertainty and must be remedied. The Agency replies to the criticisms made by the Court. It states in particular that at the beginning of 2003, it put in place a revised procedure to bring the processing of inspection fees in line with the principle of annuality. Improvements have been made to the financial accounts in the perspective of the implementation of the new Financial Regulation. Lastly, there shall be improved internal control procedures for verification of invoices, including checklists and intensified training of staff on financial procedures and controls.