2006 discharge: European Medicines Agency EMEA

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The Committee on Budgetary Control adopted the report by Hans-Peter **MARTIN** (NI, AT) recommending that the Parliament grant the Director of the European Medicines Agency discharge in respect of the implementation of its budget for the financial year 2006.

The parliamentary committee notes that the final annual accounts of the Agency are as annexed to the Court of Auditors' report.

MEPs make a series of general comments on the agencies of the EU before referring to the specific case of the European Medicines Agency.

1. General comments on the majority of EU agencies: MEPs note that the budgets of the 24 agencies and other satellite bodies audited by the Court of Auditors totalled **more than EUR 1 billion** and that the number of agencies is constantly increasing. The number of agencies subject to the discharge procedure evolved from 8 in 2000 to 20 in 2006. They conclude therefore that the auditing/discharge process has become cumbersome and disproportionate compared to the relative size of the agencies and that, in the future, this type of procedure should be simplified and rationalised for decentralised agencies.

On the basis of the financial analysis, MEPs are of the following opinion:

- **Fundamental considerations**: given the constantly increasing number of agencies, MEPs request that, before the creation of a new agency, the Commission provide clear explanations regarding agency type, objectives of the agency, internal governance structure, products, services, clients and stakeholders of the agency, formal relationship with external actors, budget responsibility, financial planning, and personnel and staffing policy. They also request that each agency be governed by a yearly performance agreement which should contain the main objectives for the coming year and that the performance of the agencies be regularly audited by the Court of Auditors (and extend the financial analysis of expenditure to also cover administrative efficiency and effectiveness). More generally, MEPs take the view that, in the case of agencies which are continually overestimating their respective budget needs, technical abatement should be made on the basis of vacant posts in order to reduce the assigned revenue for the agencies and therefore also lower administrative costs of the EU. They recall that it is a serious problem that a number of agencies is criticised for not following rules on public procurement, the Financial Regulation, the Staff Regulations etc., and consider that the principal reason for this is that most regulations and the Financial Regulation are designed for bigger institutions rather than for small agencies. Therefore, it is necessary to seek a rapid solution in order to enhance the effectiveness of the legislation by grouping the administrative functions of various agencies together or by establishing implementing rules which are better adapted to the agencies. MEPs also insist that the Commission, when drafting the Preliminary Draft Budget, take into consideration the results of budget implementation by the individual agencies in former years and revise the budget requested by the particular agency accordingly. If this revision is not undertaken is not undertaken by the Commission, MEPs invite the competent committee to revise, itself, the budget in question to a realistic level. At the same time, MEPs recall that they expect the Commission to present every five years a study on the added value of every existing agency and to not hesitate to close an agency if it is deemed useless by the analysis. Such an assessment is expected as soon as possible given that this type of assessment has yet to be presented. Furthermore, MEPs insist that recommendations of the Court of Auditors should be

promptly implemented and the level of subsidies paid to the agencies should be aligned with their real cash requirements.

- **Presentation of reporting data**: noting that there is no standard approach among the agencies with regard to the presentation of information, MEPs recall that they already invitedthe directors of the agencies to accompany their annual activity report with a declaration of assurance concerning the legality and regularity of operations, similar to the declarations signed by the Directors General of the Commission. They therefore ask the Commission to amend its standing instructions to the agencies and to produce a harmonised model for presenting information, including: i) an annual report intended for a general readership on the body's operations, work and achievements; ii) financial statements and a report on implementation of the agency's budget; iii) an activity report of the Directors of the agency (as requested by the Parliament since 2005); iv) a declaration of assurance signed by the body's director.
- **General findings by the Court of Auditors**: MEPs refer to certain recurring findings by the Court, including the disbursement of subsidies paid by the Commission (not sufficiently justified estimates of the agencies' cash requirements), the non implementation of the ABAC accounting system by some agencies or the accrued charges for untaken leave which are accounted for by some agencies. They call for rapid measures in these areas as well as improvements to the internal audit procedures of the agencies. MEPs also calls on the agencies to consider an inter-agency disciplinary board, as some individual agencies have difficulty in setting up their own disciplinary boards due to their size.
- **Draft inter-institutional agreement**: MEPs recall the Commission's draft Interinstitutional agreement on the operating framework for the European regulatory agencies (see ACI/2005/2035), which intended to create a framework for the creation, structure, operation, evaluation and control of the European regulatory agencies and insist that it be completed as soon as possible. They particularly welcome the Commission's commitment to bring forward a Communication on the future of the regulatory agencies during the course of 2008.

2. Specific points concerning the European Medicines Agency: while MEPs recognise the efforts made by the Agency to accelerate the assessment of medicines that are of critical importance to public health, they criticise the fact that the utilisation rate for commitment appropriations was less than 60% in this Agency. Furthermore, a considerable amount of budget appropriations for 2006 was carried over to 2007 due to the nature of the projects dealt with by the Agency. In addition, the Agency would accumulate a large surplus since it receives a Community subsidy and fees and other revenue paid by undertakings for obtaining and maintaining Community marketing authorisations of medicines (revenue of EUR 119 million and a Community subsidy of EUR 31 million). The total surplus for 2006 therefore amounts to EUR 44 million, which, according to the Agency, is not a budgetary surplus but rather an economic outturn based on the application of accrual accounting principles. MEPs do not understand why the board is concerned about the agency receiving new tasks that would not be met with adequate financing given that the financial situation of the Agency appears to be booming.

MEPs welcome the conclusions of the first audit of the Agency in 2005, with the conclusion that the internal control system in place provides reasonable assurance regarding the achievement of the business objectives set up for the processes audited, with some exceptions.

Lastly, MEPs are aware that the preparation of the implementation of the Regulation on medicinal products for paediatric use had a considerable impact on the Agency's work in 2006 and welcome the adoption of the joint Commission/Agency document on priorities for implementation of this Regulation.