

RESOLUTION OF THE EUROPEAN PARLIAMENT**of 10 May 2012****with observations forming an integral part of its Decision on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2010**

THE EUROPEAN PARLIAMENT,

- having regard to the final annual accounts of the European Medicines Agency for the financial year 2010,
- having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2010, together with the Agency's replies ⁽¹⁾,
- having regard to the Council's recommendation of 21 February 2012 (06083/2012 – C7-0051/2012),
- having regard to Article 319 of the Treaty on the Functioning of the European Union,
- having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities ⁽²⁾, and in particular Article 185 thereof,
- having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽³⁾ establishing a European Medicines Agency, and in particular Article 68 thereof,
- having regard to Commission Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities ⁽⁴⁾, and in particular Article 94 thereof,
- having regard to Rule 77 of, and Annex VI to, its Rules of Procedure,
- having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on the Environment, Public Health and Food Safety (A7-0107/2012),
- A. whereas the Court of Auditors, in its report on the annual accounts of the European Medicines Agency for the financial year 2009, qualified its opinion on the legality and regularity of the underlying transactions,
- B. whereas in its Decision of 10 May 2011, Parliament decided to postpone its decision on granting the Executive Director of the Agency discharge in respect of the implementation of its budget for 2009 ⁽⁵⁾ but then granted it in its Decision of 25 October 2011 ⁽⁶⁾,
- C. whereas on 25 October 2011 Parliament granted the Executive Director of the Agency discharge for implementation of the Agency's budget for the financial year 2009, and in its resolution accompanying the discharge decision, *inter alia*:
 - emphasises that the discharge authority should continue to carefully monitor during the upcoming discharge procedures the level of implementation of the measures undertaken to address the Agency's serious weaknesses disclosed by the reports from both the Court of Auditors and the Internal Audit Service (IAS),

⁽¹⁾ OJ C 366, 15.12.2011, p. 27.⁽²⁾ OJ L 248, 16.9.2002, p. 1.⁽³⁾ OJ L 136, 30.4.2004, p. 1.⁽⁴⁾ OJ L 357, 31.12.2002, p. 72.⁽⁵⁾ OJ L 250, 27.9.2011, p. 173.⁽⁶⁾ OJ L 313, 26.11.2011, p. 27.

- called on the Agency to inform the discharge authority of the action taken on issues relating to effective compliance with its Code of Conduct as regards the management of conflicts of interest,
 - insisted, but also warned the Agency, that all the action mentioned in the respective audit reports, including the one for the year 2010, should be fully implemented before the start of the next discharge procedure,
- D. whereas the Court of Auditors has stated that it has obtained reasonable assurances that the annual accounts for the financial year 2010 are reliable and that the underlying transactions are legal and regular,
- E. whereas the budget of the Agency for 2010 was EUR 208 400 000, which represents an increase of 7,20 % over the financial year 2009;
- F. whereas the initial contribution of the Union to the budget of the Agency for 2010 was EUR 28 279 600 compared with EUR 36 390 000 in 2009 ⁽¹⁾, and whereas the overall contribution of the Union to the budget of the Agency for 2010 was EUR 36 600 100,

Follow-up of 2009 discharge

1. Expects the Agency to inform the discharge authority of the results of the action taken with regard to the following issues:
 - the process of adoption by the Management Board of the action plan with specific measures and a timetable for implementation to remedy the shortcomings identified in the procurement procedures;
 - the thorough verification of the effective use of the existing procedures for the identification and management of conflicts of interest for its staff and experts;

calls on the Court of Auditors to give reasonable assurances that the Agency has effectively addressed its shortcomings relating to procurement procedures, and on the IAS to give assurances the discharge authority on the effective use of existing procedures for the management of conflicts of interest for the Agency's staff and experts;
2. Calls on the Agency and on the IAS to immediately verify whether all the action specified in the audit reports, including that for 2010, were fully implemented and to inform the discharge authority accordingly;
3. Notes from the Agency that on 15 December 2011 the Management Board endorsed a proposal for the Agency to present at the June 2012 meeting of the Management Board the detailed implementing measures related to the:
 - establishment of the new structure and scope of the Advisory Committee on Procurement and Contract,
 - implementation of a multiannual procurement plan,
 - establishment of the responsibilities for the above;

insists that the Management Board sends the Action Plan to the discharge authority at the latest by 30 June 2012;

⁽¹⁾ OJ L 64, 12.3.2010, p. 445.

Budget and financial management

4. Recalls that the initial Union contribution to the Agency for 2010 amounted to EUR 26 335 100; notes however that EUR 10 265 000 coming from the recovery of surplus, was added to that amount which, as a result, makes a total Union contribution of EUR 36 600 100 for 2010;
5. Stresses that the general budget of the European Union for the financial year 2010, as definitively adopted, presents two different figures as the initial contribution of the Union to the budget of the Agency, i.e. EUR 28 279 600 and EUR 26 335 100; urges, therefore, the Commission to inform the discharge authority of the exact subsidy allocated to the Agency;
6. Acknowledges that the Agency's budget is financed both from the Union budget and from fees paid by the pharmaceutical industry when applying for, obtaining or maintaining Union marketing authorisations; finds from the Annual Activity Report that in 2010, 73 % of the revenue of the Agency is estimated to have derived from the fee revenue and that, in parallel with the increase in the fee-based revenue, the relative percentage income from the Union contribution fell from 23 % in 2006 to 14 % in 2010;
7. Finds from the Annual Activity Report that 17 exceptions were entered in the register of exceptions in 2010;
8. Notes weaknesses in the Agency's system for validating creditor claims in respect of IT contractors; takes note of the Agency's statement that the weaknesses noted by the Court of Auditors related to a human error and were corrected, that it has strengthened its *ex-ante* operational and financial control of invoices and that no further weaknesses have been detected; invites the Court of Auditors to verify and inform Parliament in this respect;

Carryover appropriations and cancellations

9. Acknowledges from the Agency's Report on budgetary and financial management that automatic carryovers to the 2011 financial year totalled EUR 41 655 049,44, or 20,90 % of the appropriation committed, and that one non-automatic carryover to the 2011 financial year was requested totalling EUR 3 500 000, or 1,68 % of the final appropriation;
10. Is concerned that the Court of Auditors has once more reported a high carryover of EUR 17 600 000 in Title II (Administrative expenditure); stresses that this situation indicates delays in the implementation of activities financed from Title II of the Agency's budget and that the Agency is not complying with the budgetary principle of annuality;
11. Notes with concern the additional comment from the Court of Auditors that only 36 % of the appropriations carried forward to 2011 correspond to expenditure accrued from 2010, while the remaining 64 % of amounts carried over did not relate to the 2010 financial year;
12. Points out that the Court of Auditors had already reported a high level of carryovers in previous financial years; notes, in particular, that in the 2009 budget the Court of Auditors reported a carryover of EUR 19 500 000 (38 % of the Agency's commitments) and in 2008 it was EUR 36 000 000 (19,7 % of the 2008 budget);
13. Establishes from the Agency's Report on budgetary and financial management that in 2010, appropriations totalling EUR 9 074 296,49 were cancelled compared with EUR 7 693 276,58 in 2009; notes the Agency's reply that the level of cancelled expenditure appropriations is a result of stringent monitoring of actual revenue and adjustments to expenditure; urges the Agency to take immediate action to reduce the level of cancelled appropriations and to adopt an Action Plan with concrete measures — including aimed at a stricter estimation of the fee income and the period to be received — and deadlines to address this persistent problem by 30 June 2012;

Procurement Procedures and Transfers

14. Ascertains from the Annual Activity Report that, in addition to the 165 specific contracts concluded under framework contracts, 70 new procurement contracts exceeding EUR 25 000 in value were concluded by the Agency during 2010;
15. Notes from the Agency's Report on budgetary and financial management that, during 2010, 13 transfers of a total amount of EUR 13 714 500 (15,29 % of the final appropriations) were approved; further notes that the Agency already adopted 10 transfers of a total amount of EUR 9 609 000 in 2009; calls on the Agency to adopt an Action Plan with concrete measures and deadlines to remedy this persistent problem;

System of remuneration for services

16. Urges the Agency to introduce a system of remuneration for services provided by national Member State authorities based on the Member States' real costs; also calls on the Agency to promptly inform the discharge authority when this system is put in place; notes in this regards that a new payment system was already presented to the Management Board at their meeting of 10 December 2009 but it, in the end, rejected the proposal;
17. Supports all efforts at the executive and administrative levels of the Agency to reform the payment system for services provided by Member States' authorities which should clearly be based on the real costs; urges the Management Board to move forward on this issue;
18. Notes that by refusing a new payment system, the Management Board accepts and takes direct responsibility for very important risks, such as non-compliance with legislative requirements, the potential financial impact of the current remuneration system, and reputation; is therefore not ready to accept this questionable attitude from the Management Board and calls on the Agency to adopt an Action Plan on this matter and to inform the discharge authority by 30 June 2012;

Human resources management

19. Urges the Agency to strengthen its recruitment processes and ensure that its documentation is correctly managed; calls in particular on the Agency to improve the documentation of the recruitment files for contract agents and on the Appointing Authority to adopt the reserve lists proposed by the selection committees;
20. Acknowledges also from the Court of Auditors that the Agency did not distinguish sufficiently between employment-agency staff and contract staff recruitment; calls therefore on the Agency to use employment-agency staff to cover short-term needs only and grant transparent access for contract staff positions;

Management of conflict of interest

21. Urges the Agency to provide central coordination for the development of a common experts' assessment methodology applicable to all national competent authorities and for its monitoring; notes that, after the Memorandum of Understanding (MoU) signed between the Agency and each national competent authority on the monitoring of the scientific level of the experts became effective on 4 July 2011, the Agency still has responsibility for developing and coordinating a common experts' assessment and experts' methodology;
22. Emphasises that the Agency needs to finalise the signing of MoUs on the independence of scientific evaluation, to amend internal procedures correspondingly, and to update the experts' database; takes note of the Agency's reply that MoUs on the independence of scientific evaluation have been signed as of October 2011 and that the experts' database was updated to allow for the direct uploading of the electronic declarations of interest into the database; calls on the Agency to inform the discharge authority of the status of implementation of these measures by 30 June 2012; also invites the IAS to inform the discharge authority when these very important recommendations are effectively implemented by the Agency;

23. Calls on the Agency to inform the discharge authority of the way in which it ensures that procedures for the involvement of experts are fully applied until the MoUs on the independence of scientific evaluation have been signed by all national competent authorities;
24. Calls on the Agency to report on its involvement in the organisation of conferences by private organisations such as the Organisation for Professionals in Regulatory Affairs;
25. Takes note from the Agency of the adoption on 1 February 2012 of the 'Decision on rules relating to Articles 11a and 13 of the Staff Regulations concerning the handling of declared interests of employees of the European Medicines Agency' by the Management Board and of the 'Decision on rules concerning the handling of declared interests of national experts on secondment, visiting experts, trainees and interims of the European Medicines Agency' by the Executive Director; calls on the Agency to inform the discharge authority of the concrete measures undertaken to implement these decisions by 30 June 2012 in order to enable Parliament to assess the procedures in place for handling potential conflicts of interest for all categories listed in the two decisions, plus the members of the Management Board;
26. Notes with concern that in the financial circuits there are also potential conflicts of interests in processing payments due to insufficient segregation of duties; urges the Agency therefore to duly take into account this very significant risk and take immediate action to address this deficiency;
27. Notes that the former Executive Director of the Agency wrote to the Agency on 28 December 2010 outlining the activities which he was intending to take up at the end of his term of office; considers the first decision of 11 January 2011, taken by the Chairman of the Agency Management Board, to authorise the new activities of the former Executive Director of the Agency to be a breach of Union rules relating to conflicts of interest, in particular with regard to Title II, Article 16, of the Staff Regulations of the Officials of the European Union; recalls that according to Title II, Article 11, and title IV, Article 91, of the Conditions of Employment of Other Servants of the European Union, this provision applies by analogy to temporary agents and to contract employees; considers the fact that the Management Board adopted limitations on the future activities of the former Executive Director on 17 March 2011 — only after strong public protest — to be clear proof that the Agency did initially not apply the Staff Regulations properly, which in turn raises serious questions about their application of the rules in general; asks the Executive Director to present a detailed report on the implementation of Article 16 of the Staff Regulations within the Agency;
28. Is seriously concerned by the failure of the Agency and its Management Board to effectively address the matter of conflict of interests; takes note that in April 2012 the Agency adopted a revised policy on the handling of conflicts of interests of Scientific Committee members and experts, as well as a breach of trust procedure for Committee members and experts; insists that implementation and concrete results are the only elements to prove the efficiency of the new policy and procedure; believes that the Agency should verify, during 2012, all declarations of interest of experts and Scientific Committee members; therefore, calls on the Agency to provide data — figures and names included — following the enforcement of this procedure; calls also on the Agency to have verified at least 75 % of the experts' declarations of interest and at least 75 % of the Scientific Committee members' declarations of interest and to provide the discharge authority with the verification results and with an Action Plan with a calendar concerning the rest of the verification process for declarations of interest by the end of August 2012;
29. Recalls that, following the employment of the Agency's former Executive Director by a consultancy that advises, among others, pharmaceutical companies almost immediately after he left the Agency, the discharge authority raised concerns over the actual independence of the Agency and the way in which its Management Board implemented Article 16 of the Staff Regulations; is furthermore concerned by the allegations that the Agency's former Executive Director created his own consultancy firm while still in office; calls on the Agency to provide the discharge authority with further information on this matter by 30 June 2012;
30. Urges the Court of Auditors to finalise and present its current audit of conflict of interest in the Agency;

31. Regrets the fact that many of the experts failed to publish their declarations of interests, and that the comparison of declarations of interests published by the relevant national agencies and by the Agency shows significant differences in some cases; deplores, furthermore, the fact that at least one member of the Management Board of the Agency, also substitute member of the Committee for Medicinal Products for Human Use, failed to declare his recent management responsibilities in a pharmaceutical firm;
32. Welcomes the Agency's initiative to publish the declarations of interests of its staff occupying management positions and of the experts involved in the evaluation of medicinal products on its website; notes with interest that the list of experts also indicates their risk level in terms of conflict of interest; believes that at least the previous working places – professional background – should also be published along with the declarations of interest to allow verification of the declarations of interest and identify possible conflicts; therefore invites the Agency to provide Parliament with information on the status of implementation of these measures by 30 June 2012;
33. Urges the Agency to carry out checks on the declarations of interests submitted to it, and a detailed check on a random basis, notably by implementing a system under which declarations are cross-checked against information held by industry and by the relevant national agencies;
34. Is nevertheless concerned by the Agency's approach vis-à-vis the scrutiny of declarations of interest, which is primarily based on trust rather than on verification; is notably concerned by the fact that the comparison of the experts' declaration of interest published by the relevant national agencies and by the Agency reveals significant discrepancies in some cases; therefore calls on the Agency to establish a genuine mechanism enabling proper scrutiny of the declarations of interest received by the Agency and to inform the discharge authority on this matter by 30 June 2012;
35. Urges the Agency to apply its conflict of interest policy to its Management Board;
36. Notes that the Agency has been audited by the Court of Auditors in the framework of the Special Report on conflicts of interest management in the Union agencies; acknowledges from the Court of Auditors that the above-mentioned Special Report will be published by the end of June 2012; is of the opinion that, given the extent of criticisms questioning conflict of interest issues in the Agency, the decision on discharge should be postponed until the publication of the Special Report to take into account the findings of the Court of Auditors in this respect;
37. Considers that the effective management of conflict of interest is crucial to maintain public trust in the work of the Agency;
38. Acknowledges the Agency's willingness to publish the Declarations of Interests of experts involved in the evaluation of medicinal products; but deplores the fact that many of the experts have yet to publish their Declarations of Interests;
39. Takes note of the fact that the Management Board adopted limitations on the subsequent professional activities of the former Executive Director on 17 March 2011 after public protest supported by Parliament regarding its decision in January 2011 to authorise his new activities fully; recalls in this context that a delegation of the Committee on the Environment, Public Health and Food Safety visited the Agency in June 2011 to follow up this case and to receive further information on the improved procedures; recalls, furthermore, that the Committee held an exchange of views with the Executive Director — designate in July 2011 where the issue was addressed again in order to avoid future recurrences;

Performance

40. Considers the assessment of the adequacy and effectiveness of the systems in place to support the provision of scientific advice for human medicines in the Agency as an important tool to measure the Agency's performance;

41. Takes note of the increased number of products and services (opinions, reports, scientific advice, inspections) compared with 2009; is also satisfied with the implementation of Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products ⁽¹⁾ and encourages the Agency to continue its action to provide incentives for research, development and placing on the market of designated orphan medicinal products;

Internal audit

42. Acknowledges from the Agency that 11 'very important' recommendations from the IAS still need to be implemented; notes that one of them has been reported as implemented by the Agency and is now under the IAS review;
43. Is concerned that seven of these 'very important' recommendations have been delayed by up to more than 12 months; notes that these recommendations concern:

- the compliance with Article 110 of the Staff Regulations;
- the recruitment process;
- the use of databases;
- the definition of rules on filing for products;
- the guidelines on the management of potential conflicts of interest of staff;
- the procedures on involvement of experts;
- the segregation of duties in the financial circuits;

urges the Agency therefore to promptly address these deficiencies identified by the IAS and to inform the discharge authority of the measures taken;

44. Is further concerned that the Agency rejected two 'very important' recommendations relating to:

- the fees paid to national agencies;
- the reduction in the number of consultants working in-house;

urges the Agency to explain immediately to the discharge authority the rejection of these two recommendations;

45. Notes that if the IAS in its follow-up report of September 2010 continues to find 'inadequate assessment of the independence of the experts', the Executive Director should publish a list of all the authorised medicinal products concerned and report how the Agency intends to rectify these procedures;
46. Draws attention to its recommendations from previous discharge reports, as set out in the Annex to this resolution;
47. Refers, in respect of the other observations accompanying its Decision on discharge, which are of a horizontal nature, to its resolution of 10 May 2012 ⁽²⁾ on the performance, financial management and control of the agencies.

⁽¹⁾ OJ L 18, 22.1.2000, p. 1.

⁽²⁾ Texts adopted, P7_TA(2012)0164. (see page 388 of this Official Journal).

EUROPEAN PARLIAMENT RECOMMENDATIONS OVER PAST YEARS

European Medicines Agency	2006	2007	2008	2009
Performance	n.a.	<ul style="list-style-type: none"> — The principle of sound financial management was not rigorously fulfilled: the Agency's cash forecast had not been prepared properly — The Agency carries out its operations in two locations, exposing it to additional costs (direct posts: EUR 450 000) 	<ul style="list-style-type: none"> — Good results in having put in place sophisticated activity-based budgeting and user-satisfaction monitoring — Calls on the Agency to reassess its brokerage policy in light of the financial risks incurred throughout the year — The Agency carries out its operations in two locations, exposing it to additional costs 	<ul style="list-style-type: none"> — Unacceptable that the Agency does not apply the relevant rules for management of conflicts of interest effectively — 12 very important & 1 critical recommendations from several earlier IAS Annual Audit Reports were still not implemented in 2009 Unacceptable that the Agency is not complying with its Code of Conduct, urges the Agency to document & assess its controls & file the relevant allocation decisions which must be made available on its website — Urges the Agency to inform the discharge authority of the steps it has taken to ensure the independence of its experts since its inception — Asks the Agency to complete & regularly update the European Experts Database as required by Regulation (EC) No 726/2004
Carry-over of appropriations	The budgetary principle of annuality was not strictly observed: the utilisation rate for commitment appropriations was less than 60 % more than 40 % of the commitments were carried over to the financial year 2007	The agency had difficulties in the programming, the budgeting of its activities, and their implementation: EUR 32 000 000 euro were carried over and EUR 4 000 000 were cancelled: Calls on the agency to fulfil the principle of annuality	Calls on the Agency to fulfil the annuality principle: the budget appropriations carried over and cancelled have amounted respectively to EUR 36 000 000 (19,7 % of the budget) and EUR 9 700 000 (5,3 % of the budget)	Court of Auditors reports a carryover of EUR 19 500 000 (38 % of Agency's commitments), EUR 14 800 000 of this was for activities not yet implemented at year end, indicates delays in the implementation of activities financed from Title II. Agency is not in accordance with budgetary principle of annuality
Procurement procedures	n.a.	<ul style="list-style-type: none"> — Transparency issues at the level of selection criteria and at the level of the evaluation methods for the price criteria and joint procurement procedure — Recalls on improving procurement management 	Calls on the Agency to improve the quality of its procurement procedures so as to put an end to the shortcomings: i.e. as regards the application of evaluation methods for the price criteria and as regards the essential need for justifications for the choice procedure	<ul style="list-style-type: none"> — Concerned that the Court of Auditors findings of errors in the procurement procedures corresponding to a significant amount of the Agency's total budget for the financial year of 2009. Shortcomings in evaluation criteria such as price and choice of procedures — Urges the Agency to improve the quality of its procurement procedures in order to put an end to the shortcomings identified by the Court of Auditors

European Medicines Agency	2006	2007	2008	2009
				<ul style="list-style-type: none"> — Calls on the Agency to set up a multiannual procurement plan — Calls on the Agency to ensure the results of procurement procedures are verified before contracts are awarded
Revenue from fees	The Agency has not been able to make a comprehensive analysis of the costs incurred by Member States' rapporteurs in order to obtain an objective and documented basis on which to adapt its payments to them, and consequently the fee charged to its customers: This situation was in breach of the Fee Regulation	Transparency issues on the amount repaid to the Member States' rapporteurs	Calls on the Commission to evaluate the Agency's endemic high level of cash holdings (EUR 41 887 000)	Calls on the Agency to ensure better coordination between its financial & scientific services in order to remedy the unacceptable long day of recovery orders
Internal Audit	n.a.	n.a.	Calls on the Agency to fulfil a 'critical recommendation' made the Commission's Internal Audit Service related to the area of experts' conflicts of interests, and other eight 'very important' recommendations in the areas of documentation of conflicts of interest for the Agency's staff, databases used to support the administrative procedures for evaluation and development of guidelines for filing and full implementation of such guidelines	<p>Unacceptable that the Executive Director's statement of assurance does not mention any reservations which is inconsistent with the undertaking given in its Code of Conduct adopted by the Agency in the light of the statements of assurance from the IAS & the Court of Auditors</p> <p>Asks the Agency to forward the IAS reports since 2007 to the discharge authority by 30 June 2011</p> <p>Urges the Agency to rapidly implement the IAS recommendations, provide the discharge authority with an overview of measures taken & implemented</p>