# Procedure file

## Basic information

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| DEC - Discharge procedure | 2004/2056(DEC) | Procedure completed |
| 2003 discharge: European Agency for the Evaluation of Medicinal products<br><br>Subject<br>8.70.03.07 Previous discharges | | |

## Key players

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|---|---|---|---|
| European Parliament | Committee responsible | Rapporteur | Appointed |
| | CONT Budgetary Control | | 26/07/2004 |
| | | PSE AYALA SENDER Inés | 22/09/2004 |
| | | | 22/09/2004 |
| | | PSE AYALA SENDER Inés | |
| | | Verts/ALE SCHLYTER Carl | |
| | Committee for opinion | Rapporteur for opinion | Appointed |
| | ENVI Environment, Public Health and Food Safety | | 27/07/2004 |
| | | PSE HAUG Jutta | |
| Council of the European Union | Council configuration | Meeting | Date |
| | Economic and Financial Affairs ECOFIN | 2646 | 08/03/2005 |

## Key events

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|---|---|---|---|
| 27/07/2004 | Non-legislative basic document published | N6-0212/2004 | Summary |
| 10/01/2005 | Committee referral announced in Parliament | | |
| 16/03/2005 | Vote in committee | | |
| 16/03/2005 | Additional information | | Summary |
| 23/03/2005 | Committee report tabled for plenary | A6-0074/2005 | |
| 12/04/2005 | Results of vote in Parliament | | |
| 12/04/2005 | Debate in Parliament | | |
| 12/04/2005 | Decision by Parliament | T6-0105/2005 | Summary |
| 12/04/2005 | End of procedure in Parliament | | |

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| 27/07/2005 | Final act published in Official Journal | | |

## Technical information

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| Procedure reference | 2004/2056(DEC) |
| Procedure type | DEC - Discharge procedure |
| Legal basis | Rules of Procedure EP 100 |
| Stage reached in procedure | Procedure completed |

## Documentation gateway

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|---|---|---|---|---|---|
| Non-legislative basic document | | N6-0212/2004 | 27/07/2004 | OS | Summary |
| Court of Auditors: opinion, report | | C324/2004<br>OJ C 324 30.12.2004, p. 0001 | 30/12/2004 | CofA | Summary |
| Committee opinion | ENVI | PE353.298 | 07/02/2005 | EP | |
| Supplementary non-legislative basic document | | 06860/2005 | 08/03/2005 | CSL | Summary |
| Committee report tabled for plenary, single reading | | A6-0074/2005 | 23/03/2005 | EP | |
| Text adopted by Parliament, single reading | | T6-0105/2005<br>OJ C 033 09.02.2006, p. 0029-0251 E | 12/04/2005 | EP | Summary |
| Commission response to text adopted in plenary | | SP(2005)2124 | 19/05/2005 | EC | |

## Final act

Budget 2005/543
OJ L 196 27.07.2005, p. 0093-0093 Summary

# 2003 discharge: European Agency for the Evaluation of Medicinal products

PURPOSE : presentation of the financial statements and the balance sheets for the European Agency for the Evaluation of Medicinal Products for the financial year 2003.

CONTENT : this report presented by the European Agency for the Evaluation of Medicinal Products presents the financial statements and balance sheets of its activities in 2003.

The appropriations entered in the final budget amount to EUR 84.2 million with a Community contribution of 23% (excluding subsidy for orphan medicines).

In terms of the staffing policy, the Agency, whose headquarters are in London (UK), officially provided 287 posts. 256 are occupied with + 48 other posts (auxiliary contracts, national experts on secondment, local and temporary staff). Therefore, there are a total of 304 assigned to operational and administrative duties.

In 2003, the Agency concentrated on the scientific evaluation of medicinal products.

As far as medicinal products for human use are concerned :

- Applications for marketing authorisations: 39;

- Favourable opinions: 39;

- Average evaluation time: 190 days;

- Opinions after authorisation: 941;

- Pharmacovigilance: 45 538 reports;

- Periodic reliability reports: 276;

- Monitoring measures: 1 025;

- Scientific opinions: 65;

- Procedures for mutual recognition: 4 080.

On the issue of Veterinary Medicinal Products:

- New applications: 10;

- Applications in respect of variants: 64;

- Inspection: 76.

## 2003 discharge: European Agency for the Evaluation of Medicinal products

Having examined the revenue and expenditure account for the financial year 2003, the balance sheet of revenue and expenditure at 31 December 2003 of the European Agency for the Evaluation of Medicinal Products and the Court of Auditors' report on the annual accounts of the Agency, the Council recommends that the European Parliament give a discharge to the Director of the Agency in respect of the implementation of the budget for the financial year 2003.

To recall, EUR 6.0 million (88%) of the EUR 6.8 million in appropriations carried forward from the financial year 2002 to the financial year 2003 have been used. EUR 16.1 million in appropriations have been carried forward from the financial year 2003 to the financial year 2004 and EUR 3.3 million have been cancelled.

Observations in the Court of Auditors' report in relation to the financial year 2003 call for certain comments by the Council, which are annexed to this Recommendation.

The Council notes that the Court has been able to issue a statement of reasonable assurance on the reliability of the Agency's annual accounts for the financial year 2003. However, it regrets that in respect of the reasonable assurance as to the legality and regularity of the underlying transactions, taken as a whole, the Court has excluded some situations concerning tenders and negotiated procedure for contracts.

The Council shares the Court's concerns on the procurement procedures applied by the Agency: whereas the general rules provide for a committee for the evaluation of tenders to be set up for any contract involving an amount exceeding EUR 13 800, the Agency sets this threshold at EUR 75 000.

The Council urges the Agency to pursue the reinforcement of the implementing rules on the award of contracts in line with the provisions of the general Financial Regulation and its implementing rules. Moreover, in certain negotiated procedures, the choice of supplier was based on the criteria of "former experience with the contractor", which is not provided for in the implementing rules for the financial regulation.

The Council asks the Agency to remedy its shortcomings regarding the criteria of choice of contractor. In this context, it notes that the Agency has aligned its implementing rules with the framework Financial Regulation applicable to Agencies and with the Commission's implementing rules.

The Council notes with satisfaction that the Agency has finally set up a new asset management system enabling the inventory data of all assets, tangible and intangible, to be consistent with the accounting data.

## 2003 discharge: European Agency for the Evaluation of Medicinal products

EP: decision of committee responsible, 1st reading/single reading

The committee adopted the report by Inés AYALA SENDER (PES, ES) and Carl SCHLYTER (Greens/EFA, SE) giving discharge to the Director of the European Agency for the Evaluation of Medicinal Products for the 2003 financial year.

In its accompanying comments, the committee made a number of general points addressed to the Commission, the Agencies and the Court of Auditors (ECA):

- before the Commission defines the framework conditions for the use of regulatory agencies, an interinstitutional agreement should spell out common guidelines;

- the Commission should carry out a cross-cutting analysis, on a standard three-year cycle, of the coherence of agency activity with EU policy in general. It should also assess "the broader European added value" of the Agencies' work in their respective fields. Before any decision is taken to propose the creation of a new agency, the need for such an agency should be carefully evaluated, bearing in mind existing structures and the principles of subsidiarity, budgetary austerity and simplification of procedures;

- the Agencies were urged to comply fully with the budgetary principles set out in the Financial Regulation, further strengthen their internal management and control procedures and pay "special attention" to procedures for the award and management of contracts. They should also step up cooperation with each other, avoid duplication of work and develop a comprehensive strategy for making the results of their work available to the general public;

- the ECA and the Agencies were urged to strengthen their cooperation and establish a methodology "that prepares the ground for a positive budget discharge from the start of the process".

## 2003 discharge: European Agency for the Evaluation of Medicinal products

The European Parliament adopted a resolution drafted by co-rapporteurs Inés AYALA SENDER (PES, ES) and Carl SCHLYTER

(Greens/EFA, SE) giving discharge to the Executive Director of the European Agency for the Evaluation of Medicinal Productsin respect of the implementation of its budget for the financial year 2003. (Please see the summary of 16/03/05.)

Parliament?s resolution is in two parts: the first concerns the discharge itself and the second part deals with an accompanying resolution on the management and implementation of the budget. The accompanying resolution also carries general points addressed to the Commission and the Agencies.

Parliament noted the Agency's efforts in 2004 aimed at strengthening its inventory system and the fact that all its assets are now entered in the new management system in compliance with the Commission's harmonised accounting plan. It stated that the Agency must build on measures already taken in order to respond to the Court of Auditors observation as regards the application of negotiated procedures in procurement.

It also asked the Agency and national authorities to complete work the European-wide pharmacovigilance reporting system (EudraVigilance database), which is still not fully operational.

Whilst Parliament welcomed the Agency's equal opportunities commitment, it regretted the absence of an equality plan. Parliament noted that the EMEA is the only Agency with more women than men in grade A.

Finally, Parliament commended the Agency's commitment to transparency and measures taken to improve its strategy for information and communication to patients and health professionals.

Parliament went on to make some general observations common to all the agencies. The principal points may be summarized as follows:

General points addressed to the Commission and the Agencies: Parliament supported the Commission?s efforts to establish a limited number of models, at least for future ?regulatory? agencies. It took the view that the structure of current and future agencies merited in-depth consideration at inter-institutional level. Before the Commission defines the framework conditions for the use of regulatory agencies, an inter-institutional agreement should spell out common guidelines. Parliament invited the Commission to perform by the end of 2005 a cross-cutting analysis of the evaluations carried out on individual Agencies in order to:

- reach conclusions with regard to the coherence of Agency activity with EU policies in general and as regards the synergies existing or to be developed between the agencies and Commission departments and the avoidance of overlapping between them;

- make an assessment of the broader European added value of the Agencies' outputs in their respective area of activity and of the relevance and effectiveness of the Agency model in implementing or contributing to EU policies;

- determine the impact of the Agencies? actions in terms of the proximity and visibility of the EU to its citizens.

In parallel with this exercise, the Commission should present proposals for changes to be made in the existing Agencies? Constituent Acts with a view to optimising its relationship with the Agencies. Before any decision is taken to propose the creation of a new agency, the Commission must undertake a strict evaluation of the added value of the function of this agency, bearing in mind existing structures, the principles of subsidiarity, budgetary austerity and the simplification of procedures.

General points addressed to the Agencies:

Parliament wanted to receive from each of the Agencies, the report summarizing information on the audits carried out by the Internal Auditor, the recommendations made and the action taken on these recommendations in accordance with Regulation 2343/2002/EC. Agencies should also make further efforts to apply correctly the staff regulations and rules applicable to other civil servants with regard to their staff. Parliament made some remarks on the imbalance between men and women in high-grade positions in the agencies, and stated that relevant provisions on equal opportunities must be observed.

In response to the relevant observations of the Court of Auditors, the Agencies must comply fully with the budgetary principles as set out in the Financial Regulation, in particular those of unity and budgetary accuracy.

Parliament went on to encourage the Agencies to strengthen their co-operation, thus opening up opportunities for developing synergies, and avoiding duplication of work. Parliament expected to be informed regularly on this issue.

It called on the Agencies to pay special attention to procedures for the award and management of contracts, and to strengthen their internal control procedures. Parliament suggested the setting-up of specialised units entrusted with the task of advising, on the basis of risk analysis, on how best to prepare contract award procedures.

General points addressed to the European Court of Auditors and the Agencies:

Parliament asked Court of Auditors and the Agencies to strengthen their co-operation in order to enhance the procedures and technical tools to improve the sound management of all the budgetary and finance issues. They should do this in order to establish a methodology that prepares the ground for a positive budget discharge from the start of the process.

## 2003 discharge: European Agency for the Evaluation of Medicinal products

OBJECTIVE: granting of discharge for implementing the EU?s general budget for 2003 ? European Medicines Agency.

LEGISLATIVE ACT: Decision 2005/543/EC of the European Parliament concerning the discharge for implementing the general budget of the EU for the 2003 financial year ? European Medicines Agency.

CONTENT: With this Decision, the European Parliament grants discharge to the Director of the European Medicines Agency for the implementation of the budget for the 2003 financial year.

This decision is in line with the European Parliament?s resolution adopted on 12 April 2005 and comprises a series of observations that form an integral part of the discharge decision (please refer to the summary of the opinion of 12/04/2005).