

Basic information	
2006/2161(DEC) DEC - Discharge procedure	Procedure completed
2005 discharge: European Agency for the Evaluation of Medicinal Products	
Subject 8.70.03.07 Previous discharges	

Key players			
European Parliament	Committee responsible		Rapporteur
	CONT Budgetary Control		HERCZOG Edit (PSE)
	Committee for opinion		Rapporteur for opinion
	ENVI Environment, Public Health and Food Safety		HAUG Jutta (PSE)
Council of the European Union	Council configuration	Meetings	Date
	Economic and Financial Affairs ECOFIN	2787	2007-02-27
European Commission	Commission DG	Commissioner	
	Budget	KALLAS Siim	

Key events			
Date	Event	Reference	Summary
31/10/2006	Non-legislative basic document published	N6-0029/2006	Summary
29/11/2006	Committee referral announced in Parliament		
26/03/2007	Vote in committee		Summary
30/03/2007	Committee report tabled for plenary	A6-0099/2007	
24/04/2007	Decision by Parliament	T6-0120/2007	Summary
24/04/2007	Results of vote in Parliament		
24/04/2007	Debate in Parliament		
24/04/2007	End of procedure in Parliament		

15/07/2008	Final act published in Official Journal		
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Technical information	
Procedure reference	2006/2161(DEC)
Procedure type	DEC - Discharge procedure
Legal basis	Rules of Procedure EP 102
Stage reached in procedure	Procedure completed
Committee dossier	CONT/6/42413

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE384.440	09/02/2007	
Committee opinion	ENVI	PE382.438	28/02/2007	
Amendments tabled in committee		PE386.407	08/03/2007	
Committee report tabled for plenary, single reading		A6-0099/2007	30/03/2007	
Text adopted by Parliament, single reading		T6-0120/2007	24/04/2007	Summary

Council of the EU

Document type	Reference	Date	Summary
Supplementary non-legislative basic document	05711/2007	07/02/2007	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
OS	Non-legislative basic document	N6-0029/2006 OJ C 266 31.10.2006, p. 0004	31/10/2006	Summary
CofA	Court of Auditors: opinion, report	N6-0001/2007 OJ C 312 19.12.2006, p. 0001	19/12/2006	Summary

Additional information		
Source	Document	Date
European Commission	EUR-Lex	

Final act

2005 discharge: European Agency for the Evaluation of Medicinal Products

2006/2161(DEC) - 24/04/2007 - Final act

PURPOSE: to grant discharge to the European Medicines Agency for the financial year 2005.

LEGISLATIVE ACT: Decision 2008/521/EC of the European Parliament on the discharge for the implementation of the budget of the European Medicines Agency for the financial year 2005.

CONTENT: with the present decision, the European Parliament grants discharge to the Executive Director of the European Medicines Agency for the implementation of the Agency's budget for the financial year 2005.

This decision is in line with the European Parliament's resolution adopted on 24 April 2007 and comprises a series of observations that form an integral part of the discharge decision (please refer to the summary of the opinion of 24/04/2007).

2005 discharge: European Agency for the Evaluation of Medicinal Products

2006/2161(DEC) - 24/04/2007 - Text adopted by Parliament, single reading

The European Parliament adopted a resolution drafted by Edit **HERCZOG** (PSE, HU), and granted the executive director of the European Medicines Agency discharge for the implementation of the Agency's budget for the financial year 2005. It then approved the closing of the accounts of the Centre for the financial year 2005.

The Parliamentary resolution is divided into two parts. The first contained general points, and concerned the majority of EU Agencies requiring individual discharge. The second part contained specific points relating to the Agency.

General points: Parliament considers that the ever-growing number of Community Agencies and the activities of certain of them do not seem to form part of an overall policy framework, and that the remits of some Agencies do not always reflect the real needs of the Union. Accordingly, it invites the Commission to define an overall policy framework for the setting up of new Community Agencies and to present a cost-benefit study before the setting up of any new agency, while being careful to avoid any overlap of activities between Agencies or with the remits of other European organisations. Parliament calls on the Court of Auditors to give its opinion on this cost-benefit study before Parliament takes its decision, and it asks the Commission to present every five years a study on the added value of every existing Agency. ; invites all relevant institutions In the case of a negative evaluation of the added value of an Agency, all relevant institutions are asked to take the necessary steps by reformulating the mandate of that Agency or by closing it.

In view of the constantly increasing number of Agencies, Parliament feels that the Directorates-General of the Commission charged with the setting up and monitoring of Agencies must develop a common approach to the Agencies. It also asks the Commission to improve administrative and technical support to the Agencies. Parliament regretted that the negotiations on the draft interinstitutional agreement on the operating framework for the European regulatory agencies have not yet been concluded, and calls on the Commission, in consultation with the Court of Auditors, to do their utmost to ensure that the agreement is brought to a rapid conclusion. Noting that the Commission's budgetary responsibility calls for closer linking of the Agencies to the Commission, Parliament calls on the Commission and the Council to take all necessary steps to give the Commission a blocking minority in the supervisory bodies of the regulatory Agencies by 31 December 2007 and to provide for such a minority from the outset when new Agencies are set up. It invites the Court of Auditors to create an additional chapter in its Annual Report, devoted to all Agencies to be discharged under the Commission's accounts in order to have a much clearer picture of the use of EU funds by Agencies.

Parliament goes on to ask the Commission to come up with a proposal to harmonise the format of the annual reporting by the Agencies and to develop performance indicators which would allow a comparison of their efficiency. The Commission is urged to monitor and direct the management of the Agencies, especially in relation to the proper application of tender procedures, transparency of recruitment procedures, sound financial management and, most importantly, the proper application of the rules concerning the internal control framework.

Specific points concerning the European Medicines Agency: Parliament noted that for administrative expenditure (Title II) the utilisation rate for commitment appropriations was less than 90 %, with more than 40 % of the commitments made being carried over to the following financial year. It also noted that the budget of the Agency has grown considerably between 2003 and 2005 due to the enlargement of the EU and new tasks, and pronounced itself very pleased with the increased appropriations for, and the full implementation of, the Orphan Drugs budget line. Parliament invited the Agency to make sure that only staff members with delegation rights have access to the corresponding computer system. It demanded that contract award procedures should be transparent and follow the guiding rules including in the IT area, and it asked the Agency to inform Parliament about the new call for tender concerning bank contracts according to standard rules as soon as possible.

Parliament went on to point out that the new pharmaceuticals legislation, adopted in 2004, has had a considerable impact on the Agency's work, management structures and staff, congratulating the Agency on successfully adapting to the new regulatory framework. It welcomed the Agency's efforts to provide more scientific advice at early stages of the development of new medicines as well as the introduction of measures to accelerate the assessment of medicines that are of critical importance to public health, noting the work done by the Agency to facilitate a quick assessment of vaccines in the event of an influenza pandemic.

Lastly, Parliament wanted the Agency to commission an independent external evaluation of its achievements before 1 January 2010 and every five years thereafter. The Agency should draft such recommendations to the Commission and Parliament as may be necessary regarding changes in the Agency. The evaluation and the recommendations must be made public.

2005 discharge: European Agency for the Evaluation of Medicinal Products

2006/2161(DEC) - 27/02/2007

The Council, on the basis of intensive preparatory work, approved a recommendation on the discharge to be given to the Directors of the 16 European Union agencies for implementation of their budget for 2005. The recommendation will be submitted to the European Parliament, in accordance with the budgetary discharge procedure.

The Council makes reference to the **Court of Auditors report on translation expenditure** (see summary of the document annexed to the Commission's discharge procedure [DEC/2006/2070](#) dated 8 February 2007 06162/2007). It adopted the following conclusions:

Firstly, it states that it welcomes the Court's special report on translation expenditure - which amounted to EUR 511 million in 2005 - incurred by three institutions in particular as it covers the period of the accession of 10 new Member States, increasing the number of official and working languages to 21. In this context, it underlines the importance of the translation of documents in a European Union **multilingual environment** with equal treatment of the languages of its Member States.

It emphasises that translation demands are to be met in time and in adequate quality, as an essential part of the legislative process keeping the cost under control as well as having adequate procedures to give priority to essential translations which implies efficient and effective management of translation resources. It regrets, however, that in some cases politically important information which should be translated has been included in non translated annexes of documents.

The Council notes with satisfaction that the Court of Auditors stated that the institutions have generally met translation needs in the EU-15 languages in required quality inter alia by recourse to freelance translators. It regrets that all three institutions have faced structural difficulties in providing a sufficient volume and acceptable quality into the EU-10 languages. It expects the institutions to further enhance the degree of multilingualism as regards the information provided on their websites.

Moreover, the Council regrets the fact that the institutions, with the exception of the Commission for 2002, have not calculated their total costs or the average cost per page translated and invites them to do so from now on and inform the budgetary authority on a regular basis.

It notes with concern the fact that the productivity of the EU translation services is much lower than in the private sector, partly due to more effective use of IT tools in the private sector, although the quality of internal translation is recognised to be higher. It notes the long term action plan by the Council General Secretariat to increase its productivity by reducing the number of "full-time equivalent" in the EU-15 language units.

Inter-institutional cooperation: the Council advocates inter-institutional cooperation being reinforced to all institutions in order to improve the efficiency and the procedures and to reduce the costs in the field of translations. It urges the institutions to set up proper forecasting system and improve the system of workload balancing in order to make better use of spare capacity and to avoid unnecessary outsourcing. In 2005, according to the Court, EUR 11 million of freelance translation costs could have been saved by the Commission and by the Parliament by giving the non-urgent documents to be translated for other institutions. It regrets that it was not possible for the institutions to recruit enough translators in EU-10 languages which has resulted in quality and deadline problems in the EU-10 translations and it recommends that sufficient EU-10 translator resources should be ensured by measures increasing awareness and fostering interest in the Community's translation activity in the EU-10 Member States and other Candidate Countries. It recommends that similar measures be taken for Bulgaria and Romania.

The Council emphasises that future measures are to be taken by the institutions to contain the volume translated including control of the size of documents, without prejudice of equal treatment of EU official and working languages taking into account the operational effectiveness, and adoption of a fit-for-purpose approach for authorised texts for translation and encourages the institutions to improve their work planning and comply with the deadlines for requesting translations.

Lastly, the Council requests the institutions to improve the efficiency of the translation process in particular by intensifying the recourse to IT tools, reduction of secretarial support, working methods based on best practices and teleworking. It also invites the Court to examine also the translation expenditure of the other institutions and bodies.

2005 discharge: European Agency for the Evaluation of Medicinal Products

2006/2161(DEC) - 07/02/2007

Having examined the revenue and expenditure account for the financial year 2005, the balance sheet of revenue and expenditure at 31 December 2005 of the European Medicines Agency, the Council recommends the European Parliament to give a discharge to the Director of the Agency in respect of the implementation of the budget for the financial year 2005.

In doing so, the Council confirms that EUR 21.6 million (95%) of the EUR 22.7 million in appropriations carried forward from the financial year 2004 to the financial year 2005 have been used. In addition, EUR 18.8 million in appropriations have been carried forward from the financial year 2005 to the financial year 2006 and EUR 5.6 million have been cancelled.

In parallel, the Council makes accompanying comments on the discharge which should be followed up. In particular, it:

- shares the Court's observation on the **high carry-over rate** for administrative expenditure in 2004-2005 and calls on the Agency to comply with the principle of annuality;
- calls on the Agency to respect the rules on the award of contracts, especially as regards IT contracts;
- shares the Court's opinion on the need to start a **new call for tender** regarding the services provided by banks and notes from the Agency's reply that this is the case.

2005 discharge: European Agency for the Evaluation of Medicinal Products

2006/2161(DEC) - 31/10/2006 - Non-legislative basic document

PURPOSE: presentation of the final accounts of the European Medicines Agency for the financial year 2005.

CONTENT: this document published in the Official Journal of the EU sets out a detailed account of the implementation of the 2005 budget, including the revenue and expenditure and the balance sheet for the year concerned.

According to this document, the final budget amounted to **EUR 111.8 million** (in comparison to EUR 99.4 million in 2004) consisting of a 22.7% Community contribution.

As regards staffing, the Agency, whose headquarters are based in London (UK), set out a total of 379 posts in the establishment plan. 337.5 posts are currently occupied + 34 other posts (auxiliary contracts, seconded national experts, local staff, employment agency staff) totalling 371.5 posts (340 in 2004) assigned to operational, administrative and mixed tasks.

Staff expenditure accounted for EUR 41.356 million.

Throughout 2005, the Agency concentrated on coordinating the scientific evaluation of medicinal products which are subject to Community marketing authorisation procedures.

Concerning medicinal products for human use, the Agency:

- replied to 43 applications for marketing authorisations and delivered 24 favourable opinions taking an average evaluation time of 203 days as opposed to 187 days in 2004;
- delivered 1 148 opinions after authorisation;
- drafted 91 565 pharmacovigilance reports (64 186 in 2004) and 279 periodic reliability reports;
- delivered 135 scientific opinions and 8 451 procedures for mutual recognition.

Concerning veterinary medicinal products, the Agency:

- replied to 11 new applications for marketing authorisations and 70 applications in respect of variants;
- carried out 114 inspections.

As regards orphan medicinal products, the Agency:

- replied to 118 applications and gave 88 favourable opinions.

The complete version of the final accounts may be found at the following address:

www.emea.eu.int

2005 discharge: European Agency for the Evaluation of Medicinal Products

2006/2161(DEC) - 19/12/2006

This report from the Court of Auditors concerns the results of the audit carried out by the Court on the annual accounts of the European Medicines Agency for the financial year ended 31 December 2005.

The Court states that its audit was planned and performed to obtain reasonable assurance that the accounts are reliable and the underlying transactions are legal and regular.

The report shows that the appropriations entered in the final budget amount to EUR 111 835 000 with EUR 105 354 000 committed and EUR 88 489 000 paid. EUR 18 833 000 was carried over to 2006, and EUR 4 513 000 cancelled.

In its report, the Court observes that the utilisation rates for commitment appropriations (94 %) and payment appropriations (82 %) were on the whole high. For administrative expenditure (Title II), however, the utilisation rate for commitment appropriations was less than 90 %, and more than 40 % of the commitments made were carried over to the following financial year.

Other observations are as follows:

- access rights to the computer system did not always correspond to the delegations in force;
- from the end of 2004, the Agency has managed funds (approximately EUR 400 000) collected from other Agencies and bodies to finance a common support service to develop their financial management information systems. Up to 2005, these funds were not presented in the Agency's annual accounts, as was the case with other Agencies which managed the funds in earlier years following a rotational system;
- anomalies were found in the course of checks on the award of contracts, especially as regards IT contracts;
- no formal decisions concerning the appointment of evaluation committees;
- rules governing the hierarchical independence of committee members were not observed;
- evaluation committee meetings were held in the absence of some of the members, without any formal justification for their absence;
- contracts concluded with the banks have been in force for over six years even though the detailed rules for the implementation of the Agency's financial regulation lay down that there should be a new call for tenders at least once every five years.

The Agency responds point by point to the Court's observations. It notes that the high carry-over 2004-2005 on Title 2 is mainly due to the Telematics expenditure programme, which accounts for 80 % of the carry-overs. The Telematics carry-overs were high because this programme comprises a number of large and complex multi-annual projects covering the whole EU that stretched from 2004 through into 2005.

Security access has been rectified and all delegated authorising officers were instructed that they must take care to sign the right transaction (in SI2) based on the delegation decision and that they must act with due diligence in this regard.

The CSS expenditure for 2006 will be included in the EMEA budget with the first Amending Budget and the costs will be charged to the members. Disclosure of the CSS activities in 2005 has been made in note 4 of the EMEA 2005 Accounts.

The composition of evaluation committees, often made up of more than three persons, is based on the principle that bids should be evaluated by persons both independent and with appropriate expertise. In any case, a minimum of three persons participate to the meetings and the minutes for each meeting are distributed for discussion and approval. In the future, the Agency will request that minutes include a justification in case of absence of a member.

Lastly, in 2006, the Agency launched a tender for banking services. The delay mentioned by the Court is due to the fact that over the last years, the financial system of the Agency has been overhauled and it would have been too disruptive to implement a change of bank.