Basic information

2013/2215(DEC) DEC - Discharge procedure	Procedure completed
2012 discharge: European Medicines Agency (EMA) **Subject** 8.70.03.07 Previous discharges	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
CONT Budgetary Control	SARVAMAA Petri (PPE)	10/10/2013
	Shadow rapporteur KADENBACH Karin (S&D) GERBRANDY Gerben-Jan (ALDE) STAES Bart (Verts/ALE) ANDREASEN Marta (ECR) DE JONG Dennis (GUE/NGL) VANHECKE Frank (EFD) EHRENHAUSER Martin (NI)	

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	HAUG Jutta (S&D)	10/10/2013

European Commission

Commission DG	Commissioner
Budget	ŠEMETA Algirdas

Key events

Date	Event	Reference	Summary
26/07/2013	Non-legislative basic document published	COM(2013)0570	Summary
22/10/2013	Committee referral announced in Parliament		

17/03/2014	Vote in committee		
21/03/2014	Committee report tabled for plenary	A7-0227/2014	Summary
02/04/2014	Debate in Parliament		
03/04/2014	Decision by Parliament	T7-0316/2014	Summary
03/04/2014	Results of vote in Parliament		
03/04/2014	End of procedure in Parliament		
05/09/2014	Final act published in Official Journal		

Technical information

Procedure reference	2013/2215(DEC)
Procedure type	DEC - Discharge procedure
Stage reached in procedure	Procedure completed
Committee dossier	CONT/7/13880

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE521.681	27/01/2014	
Committee opinion	ENVI	PE524.566	27/01/2014	
Amendments tabled in committee		PE521.807	25/02/2014	
Committee report tabled for plenary, single reading		A7-0227/2014	21/03/2014	Summary
Text adopted by Parliament, single reading		T7-0316/2014	03/04/2014	Summary

Council of the EU

Document type	Reference	Date	Summary
Document attached to the procedure	05849/2014	05/02/2014	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2013)0570	26/07/2013	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
CofA	Court of Auditors: opinion, report	N7-0028/2014 OJ C 365 13.12.2013, p. 0150	10/09/2013	Summary

Additional information		
Source	**Document**	**Date**
European Commission	EUR-Lex	

Final act	
Budget 2014/0591 OJ L 266 05.09.2014, p. 0237	Summary

2012 discharge: European Medicines Agency (EMA)

2013/2215(DEC) - 03/04/2014 - Text adopted by Parliament, single reading

The European Parliament adopted a decision concerning the discharge to be granted to the Executive Director of the European Medicines Agency (EMA) in respect of the implementation of the Agency's budget for the financial year 2012. The vote on the discharge decision approved the closure of the accounts (in accordance with Annex VI, Article 5(1) of the Rules of Procedure of the European Parliament.

Noting that the Court of Auditors stated that it has obtained reasonable assurances that the annual accounts of the Agency for the financial year 2012 are reliable, and that the underlying transactions are legal and regular, Parliament adopted by 493 votes to 65, with 20 abstentions, a resolution containing a series of recommendations that form an integral part of the discharge decision and as well as the general recommendations that appear in the draft resolution on performance, financial management and control of EU agencies.

These recommendations are summarised as follows:

- **Reliability of the accounts - legality and regularity of transactions**: Parliament noted that the Agency applies differing recognition criteria for fee revenues and associated expenditure and that the revenue from application fees is recognised on a straight-line basis over a set time period. It also regretted that the Agency has not yet validated its accounting system in the area of intangible fixed assets, which, given the considerable investment in the development of information and communications technology (ICT), is a crucial part of the whole accounting system. It called on the Agency to inform the discharge authority on progress in this regard within the framework of the 2012 discharge follow-up. Parliament also noted with concern that in order to cover higher school fees, the Agency grants staff whose children attend primary or secondary school a top-up allowance, which amounted to some EUR 389 000 in 2012, allowances that may be considered irregular. They acknowledged that this situation is due to the lack of European Schools in the city where the Agency is based.
- **Budget and financial management**: Parliament noted that the rate of committed appropriations carried over was high for operating expenses at 27% even though it acknowledged that this relates primarily to the Agency’s planned move to a new premises in 2014 (EUR 4 million) and to the development of ICT systems (EUR 1.6 million).
- **Commitments and carryovers**: Parliament took note that the reduced amount carried over to 2013 in comparison with 2010 and 2011 and stated that this is partly related to the new building project. They reminded the Agency of the importance of respecting the budgetary principle of annuality.
- **Prevention and management of conflicts of interests and transparency**: Parliament welcomed the fact that for the second year in a row, the Agency held a public workshop on conflicts of interests, aimed at defining the right balance between ensuring the impartiality and independence of experts involved in the Agency's work and securing the best possible scientific expertise. It stated that the Agency revised its policy on the handling of conflicts of interests by the Scientific Committees' members and experts which is expected for endorsement by the Management Board in March 2014. It called on the Agency to present that revised policy to the discharge authority once adopted. Parliament also noted that the Agency works together closely with a variety of patient, healthcare and consumer organisations in order to take their opinions into account; calls on the Agency to request public disclosure regarding the funding of any patient, consumer and healthcare organisation it works with, and to carry out a conflict of interests check regarding those organisations.
- **Performance**: Parliament requested that the Agency communicate the results and impact its work has on European citizens in an accessible way, mainly through its website.

Members also made a series of observations on transfers, procurement and recruitment procedures as well as comments on internal controls.

2012 discharge: European Medicines Agency (EMA)

2013/2215(DEC) - 26/07/2013 - Non-legislative basic document

PURPOSE: presentation by the Commission of the consolidated annual accounts of the European Union for the financial year 2012, as part of the 2012 discharge procedure.

Analysis of the accounts of the **European Medicines Agency (EMEA)**.

CONTENT: this Commission document sets out the consolidated annual accounts of the European Union for the financial year 2012 as prepared on the basis of the information presented by the institutions, organisations and bodies of the EU, in accordance with Article 129 (2) of the Financial Regulation applicable to the EU's General Budget, including the European Medicines Agency (EMEA).

In 2012, the tasks and budget of this agency were as follows:

- **description of the Agency's tasks**: the European Medicines Agency, which is located in London, was created by Council Regulation (EEC) No 2309/93, which was replaced by Regulation (EC) No 726/2004 of the European Parliament and of the Council and its role is the coordination of the scientific resources made available by the national authorities in order to ensure the evaluation and supervision of medicinal products for human or veterinary use on the basis of a centralised procedure;
- **the Agency's budget for the 2012 financial year**: the Agency's budget for 2012, as presented in the Commission document on the consolidated annual accounts of the European Union, gives the following figures:
  - § **Commitment appropriations**:
    - **committed** : EUR 226 million;
    - **paid** : EUR 222 million;
    - **carried over** : 0.
  - § **Payment appropriations**:
    - **committed** : EUR 262 million;
    - **paid** : EUR 215 million;
    - **carried over** : EUR 41 million.

See also the final accounts of the EMA.

2012 discharge: European Medicines Agency (EMA)

2013/2215(DEC) - 10/09/2013 - Court of Auditors: opinion, report

PURPOSE: presentation of the EU Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2012, together with the Agency's reply.

CONTENT: in accordance with the tasks conferred on the Court of Auditors by the Treaty on the Functioning of the European Union, the Court presents to the European Parliament and to the Council, in the context of the discharge procedure, a Statement of Assurance as to the reliability of the annual accounts of each institution, body or agency of the EU, and the legality and regularity of the transactions underlying them, on the basis of an independent external audit.

This audit concerned, amongst others, the annual accounts of the European Medicines Agency (EMA).

In the Court's opinion, the **Agency's Annual Accounts fairly present, in all material respects, its financial position as of 31 December 2012** and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its financial rules and the accounting rules adopted by the Commission's accounting officer.

The Court also considers that the **transactions underlying the annual accounts** of the Agency for the financial year ended 31 December 2010 are, in all material respects, **legal and regular**.

The report confirms that resources made available to the Agency's in 2012 amounted to EUR 222.5 million.

The report also makes a series of observations on the budgetary and financial management of the Agency, accompanied by the latter's response. The main observations may be summarised as follows:

The Court's observations:

- reliability of the accounts: the Agency noted that it applies differing recognition criteria for fee revenue and associated expenditure. This is in contradiction with the matching principle. It states that it has not yet validated its accounting system in the area of intangible fixed assets. Given the considerable investment in the ICT development (2012 investments in ICT development amounted to EUR 11.6 million), this is a crucial part of the whole accounting system;
- staff: in 2011 and 2012, the Council refused salary increases for EU staff. The Commission appealed this decision to the Court of Justice which did not yet rule on the matter. Since the Agency is located in London, the salary increases in question will be paid in GBP whereas the

Agency’s accounts are prepared in Euros. Given the fluctuations in the exchange rate over the period concerned, the possible back pay to staff would lead to an estimated exchange rate loss for the Agency of EUR 2.09 million. The Agency has included this amount in the calculation of its budgetary outturn account, leading to an equivalent understatement of funds to be paid back to the Commission;

- legality of the operations: in 2012, the Agency issued cascading framework contracts for the provision of services. The procurement procedure presented some irregularities affecting the principle of transparency;
- budgetary management: the rate of committed appropriations carried over was high at 27 %, this primarily relates to the Agency’s planned move to new premises in 2014 (EUR 4 million) and the development of ICT systems (EUR 1.6 million).

The Agency's response:

- reliability of the accounts: in light of the Court’s observation the Agency will review its accounting policy on recognising fee revenue and associated expenditure to ensure future compliance with the matching principle;
- staff: the Agency states that the amount was included in the Agency's accounts following an instruction from the Accounting Officer of the EU Commission that all unrealised exchange losses should be included in the budgetary accounts as well as the financial accounts. The Agency expects to need this money in order to cover the salaries payable in GBP to EMA staff when the 2011 and 2012 rappels are adopted. The Agency is aware that DG BUDG considers the ‘rappel’ an unforeseeable expenditure, but judges this position to be untenable because the adaptation of exchange rates and weightings which are part of any ‘rappel’ is not only foreseeable, but legally required and long overdue. For the budgetary accounts the Agency applies the same methodology used to calculate the provision in the financial accounts. The Agency's primary concern is that if these figures are not included in the 2012 budgetary accounts it will find itself returning funds to the Commission when in fact those funds will be needed to pay salary liabilities once the weighting and applicable exchange rates are adapted to real levels;
- legality of operations: the Agency **does not share the view of the Court that the principle of transparency was infringed in its tender procedure**. It stated that it will make improvements on the issues highlighted by the Court to ensure even greater transparency in the future;
- budgetary implementation: the Agency noted that it has already substantially reduced its carry over levels as the equivalent carry over in 2011 was 33% and 36% in 2010 (27% in 2012). The Agency strives by respecting its operational requirements to further reduce its carry over to a level within tolerable margins of the Financial Regulation.

Lastly, the Court of Auditors’ report contains a summary of the **Agency's activities in 2012**. This is focused on the following:

- applications for marketing authorisations for 96 medicines for human use ;
- pharmacovigilance activities;
- mutual recognition procedures and decentralised procedures: started 6991; (ended 6709);
- scientific advice finalised;
- applications for paediatric investigation plans: 178 relating to 218 indications;
- applications for marketing authorisations for 13 medicinal products for veterinary use;
- 450 inspections;
- herbal medicinal product studies;
- 197 applications for orphan medicinal products (139 favourable opinions);
- requests for SME status: 684 requests and 361 applications for fee reduction or deferrals.

2012 discharge: European Medicines Agency (EMA)

2013/2215(DEC) - 05/02/2014

Having examined the revenue and expenditure accounts for the financial year 2012 and the balance sheet at 31 December 2012 of the European Medicines Agency (EMA), as well as the Court of Auditors' report on the annual accounts of the Agency for the financial year 2012, accompanied by the Agency's replies to the Court's observations, 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 2012.

The observations in the Court of Auditors' report call for certain comments by the Council which can be summarised as follows:

- in general, the Council welcomes the Court's opinion that, in all material respects, the Agency's annual accounts present fairly its financial position as at 31 December 2012 and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of the Agency's Financial Regulation and that the underlying transactions for that financial year are legal and regular.
- **Accounting system**: notwithstanding this favourable finding, the Council regrets the shortcomings identified by the Court with regard to the Agency's accounting system and urges the Agency to take swift measures to remedy the identified weaknesses.
- **Procurement procedures**: the Council also urges the Agency to take actions to remedy the weaknesses found by the Court in the Agency's procurement procedures and to address the weaknesses linked to compliance with the Staff Regulations' provisions regarding payment of **education allowances**.
- **Carry-overs of appropriations**: finally, the Council recalls that, in line with the budgetary principle of annuality, carry-overs should be strictly limited.

2012 discharge: European Medicines Agency (EMA)

2013/2215(DEC) - 21/03/2014 - Committee report tabled for plenary, single reading

The Committee on Budgetary Control adopted the report by Petri SARVAMAA (EPP, FI) in which it recommended the European Parliament to grant discharge to the Executive Director of the European Medicines Agency (EMA) in respect of the implementation of the Agency's budget for the financial year 2012.

Noting that the Court of Auditors stated that it has obtained reasonable assurances that the annual accounts of the Agency for the financial year 2012 are reliable, and that the underlying transactions are legal and regular, Members approved the closure of the Agency's accounts. They made, however, a number of recommendations that needed to be taken into account when the discharge is granted, in addition to the general recommendations that appear in the draft resolution on performance, financial management and control of EU agencies.

- **Reliability of the accounts - legality and regularity of transactions**: Members noted that the Agency applies differing recognition criteria for fee revenues and associated expenditure and that the revenue from application fees is recognised on a straight-line basis over a set time period. They also regretted that the Agency has not yet validated its accounting system in the area of intangible fixed assets, which, given the considerable investment in the development of information and communications technology (ICT), is a crucial part of the whole accounting system. They called on the Agency to inform the discharge authority on progress in this regard within the framework of the 2012 discharge follow-up. Members also noted with concern that in order to cover higher school fees, the Agency grants staff whose children attend primary or secondary school a top-up allowance, which amounted to some EUR 389 000 in 2012, allowances that may be considered irregular. They acknowledged that this situation is due to the lack of European Schools in the city where the Agency is based.
- **Budget and financial management**: Members noted that the rate of committed appropriations carried over was high for operating expenses at 27% even though they acknowledged that this relates primarily to the Agency's planned move to a new premises in 2014 (EUR 4 million) and to the development of ICT systems (EUR 1.6 million).
- **Commitments and carryovers**: Members took note that the reduced amount carried over to 2013 in comparison with 2010 and 2011 and stated that this is partly related to the new building project. They reminded the Agency of the importance of respecting the budgetary principle of annuality.

Members also made a series of observations on transfers, procurement and recruitment procedures as well as comments on internal controls.

Lastly, they acknowledged that the Agency revised its policy on the handling of conflicts of interests by the Scientific Committees' members and experts which is expected for endorsement by the Management Board in March 2014. They called on it to present that revised policy to the discharge authority once adopted. Members noted that the Agency works together closely with a variety of patient, healthcare and consumer organisations in order to take their opinions into account. They called on the Agency to request public disclosure regarding the funding of any **patient, consumer and healthcare organisation** it works with, and to carry out a **conflict of interests check** regarding those organisations.

2012 discharge: European Medicines Agency (EMA)

2013/2215(DEC) - 03/04/2014 - Final act

PURPOSE: to grant discharge to the European Medicines Agency (EMA) for the financial year 2012.

NON-LEGISLATIVE ACT: Decision 2014/591/EU of the European Parliament on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2012.

CONTENT: with this Decision, the European Parliament gives discharge to the Executive Director of the European Medicines Agency for the implementation of the Agency's budget for 2012.

The Decision is consistent with the European Parliament's resolution adopted on 3 April 2014 and includes a series of observations that form an integral part of the discharge decision (refer to the summary of the opinion of 3 April 2014).

Amongst the main observations made, Parliament highlighted the **failures as regards the legality and regularity of operations**, without calling into question its overall management.