Procedure file

Basic information

DEC - Discharge procedure	2011/2220(DEC)	Procedure completed
2010 discharge: European Medicines Agency (EMA) Subject 8.70.03.07 Previous discharges		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	CONT Budgetary Control		03/03/2011
		PPE MACOVEI Monica	
		Shadow rapporteur	
		S&D HERCZOG Edit	
		ALDE GERBRANDY Gerben-Jan	
		Verts/ALE STAES Bart	
		ECR CZARNECKI Ryszard	
		EFD ANDREASEN Marta	
		NI EHRENHAUSER Martin	
		NI HARTONG Lucas	
	Former committee responsible		
	CONT Budgetary Control		03/03/2011
		PPE MACOVEI Monica	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety		10/07/2012
		S&D HAUG Jutta	
	Former committee for opinion		
	ENVI Environment, Public Health and Food Safety		05/10/2011
		S&D HAUG Jutta	
European Commission	Commission DG	Commissioner	
	Budget	ŠEMETA Algirdas	

Key events

26/07/2011	Non-legislative basic document published	COM(2011)0473	Summary
12/10/2011	Committee referral announced in Parliament		

27/03/2012	Vote in committee		
04/04/2012	Committee report tabled for plenary	A7-0107/2012	Summary
10/05/2012	Results of vote in Parliament		
10/05/2012	Debate in Parliament		
10/05/2012	Decision by Parliament	T7-0175/2012	Summary
10/05/2012	Report referred back to committee		
26/09/2012	Vote in committee		
02/10/2012	Committee report tabled for plenary	A7-0298/2012	Summary
23/10/2012	Decision by Parliament	T7-0366/2012	Summary
23/10/2012	End of procedure in Parliament		
20/12/2012	Final act published in Official Journal		

Technical information

Procedure reference	2011/2220(DEC)
Procedure type	DEC - Discharge procedure
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	CONT/7/07238; CONT/7/09685

Documentation gateway

Non-legislative basic document		COM(2011)0473	26/07/2011	EC	Summary
Court of Auditors: opinion, report		N7-0010/2012 OJ C 366 15.12.2011, p. 0027	06/09/2011	CofA	Summary
Committee opinion	ENVI	PE476.054	24/01/2012	EP	
Document attached to the procedure		06083/2012	08/02/2012	CSL	Summary
Committee draft report		PE473.975	13/02/2012	EP	
Amendments tabled in committee		PE483.611	07/03/2012	EP	
Committee report tabled for plenary, single reading		A7-0107/2012	04/04/2012	EP	Summary
Text adopted by Parliament, single reading		T7-0175/2012	10/05/2012	EP	Summary
Committee draft report		PE491.065	20/06/2012	EP	
Amendments tabled in committee		PE494.821	12/09/2012	EP	
Committee opinion	ENVI	PE494.538	20/09/2012	EP	
Committee report tabled for plenary, single reading		A7-0298/2012	02/10/2012	EP	Summary
Text adopted by Parliament, single reading		T7-0366/2012	23/10/2012	EP	Summary

Final act

Decision 2012/802
OJ L 350 20.12.2012, p. 0082 Summary

2010 discharge: European Medicines Agency (EMA)

PURPOSE: presentation by the Commission of the consolidated annual accounts of the European Union for the financial year 2010, as part of the 2010 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 2010 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 2010, 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. The Agency operates through a network and coordinates 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;
- the Agency's budget for the 2010 financial year: the Agency's 2010 budget amounted to EUR 208.4 million, compared with EUR 194.4 million the previous year. The number of staff employed by the Agency at the end of the year was 698, as compared with 664 the previous year.

The complete version of the Agency's final accounts may be found at the following address:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/07/WC500108349.pdf

2010 discharge: European Medicines Agency (EMA)

PURPOSE: presentation of the EU Court of Auditors report on the annual accounts of the European Medicines Agency, together with the Agencys 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 Courts opinion, the Agencys Annual Accounts fairly present, in all material respects, its financial position as of 31 December 2010 and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its Financial Regulation.

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 the Agencys 2010 budget amounted to EUR 208.4 million and that the number of staff employed by the Agency at the end of the year was 698.

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

The Courts observations:

- budgetary and financial management: the Agency experienced delays in implementing Administrative expenditure of its budget. Appropriations carried forward to 2011 totalled EUR 17.6 million, 33.3 % of the corresponding appropriations. Just 36 % of the appropriations carried forward correspond to accrued expenditure of the year, meaning 64 % of the amounts carried over did not relate to the 2010 financial year. This situation was at odds with the budgetary principle of annuality;
- recruitment: the Agency did not distinguish sufficiently between employment-agency staff and contract staff recruitments;
- follow-up on previous findings: in previous reports, the Court had noted the need for the Agency to introduce a system of remuneration for services provided by national Member State authorities based on the Member States real costs. Up to now, despite some efforts by the Agency, this has not been done.

The Agencys response:

- the Agency indicates that it has continuously improved its administrative carry-over since 2008. The amounts in question for 2010 are for multiannual Telematics ICT projects. These Telematics projects are of an operational nature and as a consequence will be accounted for from 2011. Therefore from 2011/12 the Agency expects a reduction in carry-over in administrative expenditure to a maximum of around 30 % (corresponding to a reduction of EUR 10 million);
- the Agency notes that action has been taken to improve transparency by ensuring that all contract agent positions are more clearly publicised externally prior to being filled and that the EMA implementing rules on selection and recruitment of contract agents are correctly followed;
- a proposal for a new payment system was presented to the Management Board at their meeting of 10 December 2009. The

Management Board rejected the proposal. EMA will try again to instigate the discussions at forthcoming Management Board meetings and remind the Board of the need to move forward on this topic.

Lastly, the Court of Auditors report contains a summary of the Agencys activities in 2010. This is focused on the following:

- applications for marketing authorisations for 91 medicines for human use ;
- pharmacovigilance activities;
- mutual recognition procedures and decentralised procedures: started 21 433; (ended positively 11100);
- scientific advice finalised;
- applications for paediatric investigation plans: 326 relating to 403 indications;
- applications for marketing authorisations for 18 medicinal products for veterinary use;
- 300 inspections;
- herbal monographs;
- 174 applications for orphan medicinal products (123 favourable opinions);
- requests for SME status: 251 requests and 161 applications for fee reduction or deferrals.

2010 discharge: European Medicines Agency (EMA)

The Committee on Budgetary Control adopted the report by Monica Luisa MACOVEI (EPP, RO) on discharge to be granted in respect of the implementation of the budget of the European Medicines Agency for the financial year 2010. The committee calls on the Parliament to postpone its decision on granting the Executive Director of the European Medicines Agency discharge in respect of the implementation of the Agency's budget for the financial year 2010. However, they make a number of recommendations, in addition to the general recommendations that appear in the draft resolution on performance, financial management and control of EU agencies:

- Budget and financial management: Members acknowledge 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. They state 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. They also note weaknesses in the Agency's system for validating creditor claims in respect of IT contractors and invite the Court of Auditors to verify this issue and inform Parliament in this respect;
- Carryover appropriations and cancellations: Members note 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. They state that the Agency is not complying with the budgetary principle of annuality. They note 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. Members urge the Agency to take immediate action to reduce the level of cancelled appropriations and to adopt an Action Plan with concrete measures;
- System of remuneration for services: Members urge the Agency to introduce a system of remuneration for services provided by national Member State authorities based on the Member States real costs. They note 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. 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. Members are therefore not ready to accept this questionable attitude from the Management Board and call on the Agency to adopt an Action Plan on this matter and to inform the discharge authority by 30 June 2012;
- Human resources management: Members call 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. They also call 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: Members call 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. They note with concern that in the financial circuits there are also potential conflicts of interests in processing payments due to insufficient segregation of duties and urge the Agency therefore to duly take into account this very significant risk and take immediate action to address this deficiency. Members urge the Court of Auditors to finalise and present its current audit of conflict of interest in the Agency. They regret 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. They deplore, 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. They therefore call 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. They also urge the Agency to apply its conflict of interest policy to its Management Board. Lastly, Members are 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;
- Internal audit: Members acknowledge from the Agency that 11 "very important" recommendations from the IAS still need to be implemented. Efforts should be made as regards this issue.

2010 discharge: European Medicines Agency (EMA)

The European Parliament adopted by 340 votes to 268, with 14 abstentions, a decision to postpone the granting of the discharge to the Executive Director of the European Medicines Agency in respect of the implementation of the Agency's budget for the financial year 2010. The Parliament also postponed the closure of the accounts for this agency.

Parliament also adopted by 467 votes to 139, with 23 abstentions, a resolution containing observations that are an integral part of the decision to postpone the discharge.

These observations may be summarised as follows:

- Budget and financial management: Parliament 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. It notes 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. It also notes weaknesses in the Agency's system for validating creditor claims in respect of IT contractors and invites the Court of Auditors to verify this issue and inform Parliament in this respect;
- Carryover appropriations and cancellations: Parliament notes that automatic carryovers to the 2011 financial year totalled EUR 41.6 million or 20.90 % of the appropriation committed, and that one non-automatic carryover to the 2011 financial year was requested totalling EUR 3.5 million or 1.68 % of the final appropriation. It considers that the Agency is not complying with the budgetary principle of annuality. It 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. It urges the Agency to take immediate action to reduce the level of cancelled appropriations and to adopt an Action Plan with concrete measures;
- System of remuneration for services: Parliament urges the Agency to introduce a system of remuneration for services provided by national Member State authorities based on the Member States real costs. It notes in this regard that a new payment system was already presented to the Management Board at its meeting of 10 December 2009 but it, in the end, rejected the proposal. 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. Parliament 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: Parliament calls 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. It also calls on the Agency to use employment-agency staff to cover short-term needs only and to grant transparent access for contract staff positions;
- Management of conflict of interest: Parliament 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. Noting the measures taken in 2012, Parliament invites the Agency to inform the discharge authority of the concrete measures that it has taken to ensure that it can evaluate the procedures in place to manage any eventual conflicts of interest. It notes with concern that in the financial circuits there are also potential conflicts of interests in processing payments due to insufficient segregation of duties and urges the Agency therefore to duly take into account this very significant risk and take immediate action to address this deficiency.

- Former director: Parliament considers the opportunity given to the Agencys former Executive Director to engage in new activities that are in conflict with his previous position (he was recruited almost immediately after his departure from the Agency, by a consultancy firm working for pharmaceutical companies) to be a breach of Union rules relating to conflicts of interest in regard to members of scientific committees and experts, as well as a breach of trust procedure for Committee members and experts. It believes that the Agency should verify, during 2012, all declarations of interest of experts and Scientific Committee members and calls on it to provide the discharge authority with detailed information on 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. Overall, Parliament has concerns over the actual independence of the Agency. It calls for greater transparency in this regard and welcomes the fact that the Agency has decided to publish on its website the declarations of interest of experts involved in the evaluation of medicinal products even if the Agency's approach vis-à-vis the scrutiny of declarations of interest is primarily based on trust rather than on verification. It also 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.

Parliament 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. The Report will be published by the end of June 2012. It 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.

2010 discharge: European Medicines Agency (EMA)

The Committee on Budgetary Control adopted the second reading report of Monica Luisa MACOVEI (PPE, RO) on the discharge of the European Medicines Agency (EMA) which calls on the European Parliament to grant the Executive Director of the European Medicines Agency discharge in respect of the implementation of the Agencys budget for the financial year 2010.

To recall, in May 2012, Parliament postponed the discharge decision for the Agency chiefly because there was a problem of conflict of interest of some staff (as reported in the summary dated 10/05/2012).

Members approved the closure of the Agency accounts for the 2010 financial year and made a series of recommendations to take into account on the granting of the discharge:

- transparency and management of conflict of interest: Members take note that the Agency is organising for November 2012 a workshop gathering a broad range of interested parties in the view of developing the modalities of providing public access to clinical trial data with a view to strengthening transparency. They also note that the Agency has improved the scope and methodology of the systematic ex-ante and ex-post controls related to the screening of declaration of interest and that it will perform a yearly evaluation of its revised policy on declaration of interest. They invite the Agency to keep the discharge authority informed on the implementation of its revised policy on a 6-month basis;
- a revolving door case: Members underline that, in June 2012, a revolving door case occurred in the Agency, the former Head of Legal Service joined as senior counsel a US-based law firm having a number of pharmaceutical industry companies as clients. They take note that the Executive Director of the Agency launched a review of the work performed by the former Head of Legal Service and expect the Agency to inform the discharge authority on the outcomes of this review by the end of 2012;
- screening process of declarations of interest: Members welcome that the Agency proceeded to a screening process of the declarations of interest of its experts and committee members who have been actively involved in the Agencys activities between 1

January and 31 May 2012 against their curriculum vitae. They also welcome the Agencys initiative to publish on its website the declarations of interests of its staff occupying management positions as well as other initiatives going in the direction of improved transparency. However, they agree with the Agency that a high level of reliability and honesty concerning the declaration of interests can only be achieved if pharmaceutical companies themselves make public the list of experts and research centres with which they work, and the sums concerned in their financial links with them;

- for steps to be taken in cases of non-compliance: Members consider that steps have to be taken should cases of non-compliance with existing rules occur with a view to remedying the shortcomings. Either the European Parliament or the European legislator has to address these problems by changing the existing rules and regulations to eliminate possible loopholes. In the meantime, Members call on the Agency to introduce in each of its annual activity report a special section describing the actions taken to prevent and manage conflict of interest.

In general, Members welcome the agreement on the Joint Statement and Common Approach adopted in June 2012 by the European Parliament, the Council and the Commission on decentralised agencies in which certain elements of importance to the discharge have been addressed and taken up.

2010 discharge: European Medicines Agency (EMA)

PURPOSE: to grant discharge to the European Medicines Agency (EMA) for the financial year 2010.

NON-LEGISLATIVE ACT: Decision 2012/802/EU of the European Parliament on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2010.

CONTENT: with this Decision and in accordance with Article 319 of the Treaty on the Functioning of the European Union (TFEU), the European Parliament gives discharge to the Executive Director of the European Medicines Agency for the implementation of the Agencys budget for 2010.

The Decision is consistent with the European Parliaments resolution adopted on 23 October 2012 and includes a series of observations that form an integral part of the discharge decision (refer to the summary of the opinion of 23 October 2012).

Decision 2012/803/EU, adopted on the same day, approves the closure of the accounts for this Community agency for 2010.

2010 discharge: European Medicines Agency (EMA)

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 Agencys budget for the financial year 2010. The decision to grant the discharge shall also constitute the closure of the accounts for this Agency.

To recap, in May 2012, Parliament postponed the discharge decision for the Agency chiefly because there was a problem of conflict of interest of some staff (as reported in the summary dated 10/05/2012).

Parliament approved the closure of the Agency accounts for the 2010 financial year and made a series of recommendations to take into account on the granting of the discharge:

- transparency and management of conflict of interest: Parliament notes that the Agency is organising for November 2012 a workshop gathering a broad range of interested parties in the view of developing the modalities of providing public access to clinical trial data with a view to strengthening transparency. It also notes that the Agency has improved the scope and methodology of the systematic ex-ante and ex-post controls related to the screening of declaration of interest and that it will perform a yearly evaluation of its revised policy on declaration of interest. It invites the Agency to keep the discharge authority informed on the implementation of its revised policy on a 6-month basis;
- a revolving door case: Parliament underlines that, in June 2012, a revolving door case occurred in the Agency, the former Head of Legal Service joined as senior counsel a US-based law firm having a number of pharmaceutical industry companies as clients. It takes note that the Executive Director of the Agency launched a review of the work performed by the former Head of Legal Service and expects the Agency to inform the discharge authority on the outcomes of this review by the end of 2012;
- screening process of declarations of interest: Parliament welcomes the fact that the Agency proceeded to a screening process of the declarations of interest of its experts and committee members who have been actively involved in the Agencys activities between 1 January and 31 May 2012 against their curriculum vitae. It also welcomes the Agencys initiative to publish on its website the declarations of interests of its staff occupying management positions as well as other initiatives going in the direction of improved transparency. However, it agrees with the Agency that a high level of reliability and honesty concerning the declaration of interests can only be achieved if pharmaceutical companies themselves make public the list of experts and research centres with which they work, and the sums concerned in their financial links with them;
- for steps to be taken in cases of non-compliance: Parliament considers that steps have to be taken should cases of non-compliance with existing rules occur with a view to remedying the shortcomings. Either the European Parliament or the European legislator has to address these problems by changing the existing rules and regulations to eliminate possible loopholes. In the meantime, it calls on the Agency to introduce in each of its annual activity report a special section describing the actions taken to prevent and manage conflict of interest;
- report on follow-up to the discharge: Parliament calls on the Agency to introduce in its annual activity reports a special section describing the actions taken to prevent and manage conflict of interest, which should include, inter alia: i) the number of alleged cases of conflict of interest verified; ii) the number of revolving door cases; iii) the measures taken in each category of cases; iv) the number of breach of trust procedures launched and their outcomes; and v) the penalties applied.

Overall, Parliament welcomes the agreement on the Joint Statement and Common Approach adopted in June 2012 by the European Parliament, the Council and the Commission on decentralised agencies in which certain elements of importance to the discharge have been addressed and taken up.