Procedure file

Basic information

DEC - Discharge procedure	2010/2173(DEC)	Procedure completed
2009 discharge: European Medicines Agency (EMEA) Subject 8.70.03.07 Previous discharges		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	CONT Budgetary Control		23/03/2010
		S&D STAVRAKAKIS Georgios	
		Shadow rapporteur	
		PPE MACOVEI Monica	
		ALDE GERBRANDY Gerben-Jan	
		Verts/ALE STAES Bart	
European Commission	Commission DG	Commissioner	
	Budget	ŠEMETA Algirdas	

Key events

20/07/2010	Non-legislative basic document published	SEC(2010)0963	Summary
07/10/2010	Committee referral announced in Parliament		
11/04/2011	Vote in committee		Summary
15/04/2011	Committee report tabled for plenary	A7-0153/2011	
10/05/2011	Debate in Parliament		
10/05/2011	Decision by Parliament	T7-0202/2011	Summary
10/05/2011	Report referred back to committee		
03/10/2011	Vote in committee		Summary
06/10/2011	Committee report tabled for plenary	A7-0329/2011	
25/10/2011	Decision by Parliament	T7-0447/2011	Summary
25/10/2011	End of procedure in Parliament		
25/11/2011	Final act published in Official Journal		

Technical information

Procedure reference	2010/2173(DEC)
Procedure type	DEC - Discharge procedure

Other legal basis	Rules of Procedure EP 159
Stage reached in procedure	Procedure completed
Committee dossier	CONT/7/06014

Documentation gateway

Non-legislative basic document		SEC(2010)0963	20/07/2010	EC	Summary
Court of Auditors: opinion, report		N7-0012/2011 OJ C 338 14.12.2010, p. 0028	05/10/2010	CofA	Summary
Document attached to the procedure		05892/2011	03/02/2011	CSL	Summary
Committee draft report		PE450.722	09/02/2011	EP	
Amendments tabled in committee		PE460.805	09/03/2011	EP	
Committee opinion	ENVI	PE454.640	16/03/2011	EP	
Committee report tabled for plenary, single reading		A7-0153/2011	15/04/2011	EP	
Text adopted by Parliament, single reading		T7-0202/2011	10/05/2011	EP	Summary
Committee draft report		PE469.789	27/07/2011	EP	
Amendments tabled in committee		PE472.098	09/09/2011	EP	
Committee report tabled for plenary, single reading		A7-0329/2011	06/10/2011	EP	
Text adopted by Parliament, single reading		T7-0447/2011	25/10/2011	EP	Summary

Final act

Decision 2011/758
OJ L 313 26.11.2011, p. 0027 Summary

2009 discharge: European Medicines Agency (EMEA)

PURPOSE: presentation by the Commission of the consolidated annual accounts of the European Union for the financial year 2009, as part of the 2009 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 2009 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 2009, 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 2009 financial year:the Agency?s 2009 budget amounted to EUR 194.4 million, compared with EUR 182.9 million the previous year. The number of staff employed by the Agency at the end of the year was 664, as compared with 587 the previous year.

The complete version of the Agency?s final accounts may be found at the following address: http://www.ema.europa.eu

2009 discharge: European Medicines Agency (EMEA)

PURPOSE: presentation by the Court of Auditors of its report on the annual accounts of the European Medicines Agency for the financial year

2009, together with the Agency?s replies.

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

This audit also covered the annual accounts of the European Medicines Agency (EMEA).

In the Court?s opinion, the Agency?s annual accounts presented ?fairly, in all material respects?, its financial position as of 31 December 2009 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 stated that the transactions underlying Eurojust?s annual accounts for the financial year ended 31 December 2009 were, ?in all material respects, legal and regular?.

The Court considers however that this statement of assurance should be accompanied by a qualified opinion on the legality and the regularity of the transactions underlying the accounts.

Elements evoking a qualified opinion from the Court:

- lack of transparency in procurement procedures: in 2009, the Agency concluded a number of procedures for the procurement of large IT framework contracts. The audit showed errors which affected the regularity of 4 operations examined: (i) in the case of a procurement of a large framework contract for IT services (value = EUR 30 million), the conditions for applying a negotiated procedure following an open procedure where tenders were assessed to be of an unacceptable quality were not satisfied; (ii) in another case, there was a lack of evidence regarding the method used for the evaluation of the selection criteria which was thus open to interpretation; (iii) in another case of negotiated procurement with a single supplier for technical reasons, no formal invitation to tender was issued; (iv) in an another similar case, the technical specifications did not clearly define all the products to be purchased before the negotiation started.

The report confirmed that the Agency?s 2009 final budget amounted to EUR 194.389 million of which 18.7% representing a Union contribution. The number of staff employed by the Agency at the end of the year was 664.

The report also included comments on the EMEA?s budgetary and financial management, together with its replies. The main comments are as follows:

The Court?s comments:

- carry-over and cancellation of appropriations: EUR 19.5 million (representing 38%) of commitments for buildings, equipment and miscellaneous operating expenditure activities were carried forward to the budgetary year 2010. According to the accounting information, approximately EUR 14.8 million of the appropriations carried forward corresponded to activities not yet implemented at the year-end. This situation was not in keeping with the budgetary principle of annuality;
- late recovery orders;
- long-standing policy of entering into forward foreign-exchange contracts in order to hedge part (50 %) of its administrative budget against unfavourable fluctuations in the exchange rate for Sterling: this situation caused financial loss for the Agency.

The Agency?s replies:

- as regards the issue of the lack of transparency in the procurement procedures: a multiannual procurement plan will be set up and will also ensure stronger technical and procedural controls; the results of procurement procedures are verified before contracts are awarded; a comprehensive and detailed evaluation guide was used in draft form by all members of the evaluation committee. Experience with this draft evaluation guide showed that it was too strict leading to unreasonably low marks;
- significant efforts have been made to reduce its carry-overs. Taking account of the growth in overall budget, in relative terms the carry-over in Title II (operating expenditure) decreased from 42.6% (2008 to 2009) to 38.1% (2009 to 2010);
- temporary control measures have been put in place pending the new financial database SAP?s ability to automatically create and update fee data from the operational database once validation of applications is completed;
- the treasury policy has been revised, adopted and formally approved by the agency?s Audit Advisory Committee.

Lastly, the Court of Auditor?s report contained a summary of the EMEA?s activities in 2009 in the following areas:

- medicinal products for human use: applications for marketing authorisations: 96;
- pharmaco-vigilance activities;
- periodic safety update reports;
- mutual recognition procedures and decentralised procedures;
- medicinal products for veterinary use: applications for marketing authorisations: 15;
- herbal medicinal products;
- orphan medicinal products: 164 applications.

2009 discharge: European Medicines Agency (EMEA)

The Committee on Budgetary Control adopted the report by Georgios STAVRAKAKIS (S&D, EL) recommending that its decision regarding the discharge to be granted to the Executive Director of the European Medicines Agency for implementation of the Agency's budget for the

financial year 2009 be postponed.

Noting that the Court of Auditors qualified its opinion on the legality and regularity of the underlying transactions, Members postpone the closure of the Agency?s accounts. They also make a number of recommendations (in addition to the general recommendations that appear in the draft resolution on financial management and control of EU agencies - see DEC/2010/2271) that are attached to the decision to postpone the discharge:

General considerations: Members cite serious shortcomings in the responses to issues raised by the Court of Auditors such as:

- the management of procurement procedures,
- the lack of respect to, and frequent lack of, implementing procedures regarding the identification and management of conflicts of interest for its staff and experts,
- the criteria used for recruiting staff.

These could result in:

- persistent errors in the management of procurement procedures,
- potential risks to the independence of experts/staff involved in the evaluation of medicinal products that might have negative effects on public health,
- potential deficiencies in staff/experts' recruitment which could not only lead to disqualification of competent candidates but also might have adverse effects on the quality of the Agency?s scientific assessment work.

Budgetary and financial management: as far as the Agency?s management is concerned, Members make the following comments:

Procurement procedures: Members note serious errors in the procurement procedures corresponding to a significant amount of the Agency's total budget for the financial year of 2009 (notably the procurement of large IT framework contracts of an estimated value of EUR 30 million as well as two other negotiated procurements of EUR 5.3 million and EUR 4 million). They note that the Agency again failed to comply with various requirements of the relevant procurement regulations. They do not accept the Agency?s attempts to justify itself on this point and expect it to improve the quality of its procurement procedures and to draw up a multiannual procurement plan which shall ensure stronger technical and procedural controls;

Carryover appropriations: in regard to a carryover of EUR 19.5 million (38% of the Agency's commitments, approximately EUR 14.8 million of which was for activities as yet not implemented or, in some cases, goods not received), Members stress that this situation indicates delays in the implementation of activities financed from the Agency?s budget. They point out that this has also occurred in the past;

Revenue from fees: Members expect the Agency to ensure better coordination between its financial and scientific services in order to remedy the unacceptable, long delay for recovery orders;

Foreign exchange contracts: Members expect the Agency to prudently manage its longstanding policy of entering into a forward foreign exchange contract in order to hedge part of its administrative budget against unfavourable fluctuations in the sterling exchange rate; expects the Agency to manage such transactions to avoid exchange losses (such as those in 2009 of EUR 900 000). They also call for an improvement in the Agency?s treasury management;

Management of conflicts of interest: Members consider it unacceptable that the Agency does not apply the relevant rules effectively, resulting in the fact that there is no guarantee that the evaluation of human medicines is performed by independent experts. They particularly deplore the recruitment of the Agency?s former Executive Director by a consultancy that advises, among others, pharmaceutical companies on developing new medication and reducing the period to their market introduction. In their view, this casts some doubt on the actual independence of the Agency. Members await further information on this matter from the Agency and that it assesses thoroughly, before the allocation of project team leaders to products, whether the interests declared by staff members might influence their impartiality and independence. They urge the Agency, in addition, to document and assess its controls and file the relevant allocation decisions which must be made available on its website. Members stress that the Agency's reputation could be affected in cases where evaluations can be challenged on the grounds of possible conflicts of interest. They urge the Agency to inform the discharge authority of the steps it has taken to ensure the independence of its experts since its inception and wonder why the Court of Auditors? reports since 2006 make no mention of any deficiencies in this respect;

The Mediator case: Members point out that any final decision on whether or not to grant discharge cannot be taken before Parliament has been fully informed about the circumstances which led to the very late withdrawal from the market of Mediator (benfluorex), a so-called slimming pill. They expect a full and extensive report from the Agency explaining why it took 10 years from the date when the first warning of the possible dangerous side effects of this drug was communicated to the Agency, before the final decision was taken to withdraw the drug in 2009. They ask to be informed if and how the experts and staff dealing with the "Mediator case" were screened on their independence and how their interests declared were verified;

Procedures supporting the provision of scientific evaluation for human medicines: Members consider it unacceptable for the Agency to allow the information in its files on human medicines to be incomplete. They urge the Agency to guarantee that key information is easily retrieved, that all relevant guidelines on the filing system are in place, as well as to complete and regularly update the European Experts Database;

Role of the Agency and national competent authorities: Members urge the Agency to inform the discharge authority of the terms of its agreement with Member States on the roles and transfer of tasks to national competent authorities when facing subjects such as the independence of committees, experts and the evaluation process, since the agreement came into effect. They consider the Agency responsible for the implementation of pre-existing procedures on the identification and management of conflicts of interest for its experts until this agreement with Member States is fully implemented. Members emphasise that the European Medicines Agency's budget is financed both from the Union budget and fees paid by the pharmaceutical industry applying for or maintaining a Union marketing authorisation. They note, however, that the contribution from the Union budget represents only 18.7 % of the overall budget and has decreased over the years. Noting the volume of carried forward appropriations to the budget year 2010 for Title II - Buildings, equipment and miscellaneous operating expenditure activities, Members encourage the Agency to continue this process in order to apply fully the principle of annuality;

Human resources management: Members call on the Agency to ensure that sensitive tasks are not assigned to interim staff. They stress the risks of potential security breaches linked to interim staff's access to sensitive information or unawareness by interim staff of the procedure to follow. They call on the Agency to strengthen its recruitment process and ensure its documentation is correctly managed. They stress, also, that insufficient documentation in recruitment procedures reduces the possibility for the Agency to respond to allegations of unequal treatment

of candidates and/or arbitrary decisions on recruitment of staff. They consider, furthermore, that to the extent that competition is limited, resulting recruitment may not represent the optimal choice and human and that financial resources may be used inefficiently. They consider it unacceptable that the Executive Director?s statement of assurance, dated 13 May 2010, does not mention any reservations. They wonder whether these requirements were fulfilled in previous years;

Internal audit: Members note that out of the 32 recommendations of the Internal Audit Service (IAS), one is "critical" on the implementing procedures involving experts and twelve are "very important" mainly on human resources management, on management of staff's conflicts of interest. They call, therefore, on the Agency to inform the discharge authority about the precise content of these recommendations without delay;

Actions to be taken by the Agency by 30 June 2011: Members urge the Agency?s Executive Director to undertake a thorough verification of the effective use of the existing procedures regarding the identification and management of conflicts of interest for its staff and experts and to communicate the results to the discharge authority by 30 June 2011. They urge the Governing Board to swiftly adopt an action plan to remedy the shortcomings in the procurement procedures, as well as measures to improve the Agency?s management by the same date.

2009 discharge: European Medicines Agency (EMEA)

The European Parliament adopted by 626 votes to 23, with one abstention, a decision to postpone granting to the Executive Director of the European Medicines Agency discharge for the implementation of the Agency?s budget for the financial year 2009.

Noting that the Court of Auditors qualified its opinion on the legality and regularity of the underlying transactions, Parliament postpones the closure of the Agency?s accounts. It also adopted by 620 votes to 7, with 12 abstentions, a resolution in which it makes a series of recommendations (in addition to the general recommendations that appear in the draft resolution on financial management and control of EU agencies - see DEC/2010/2271) that are attached to the decision to postpone the discharge:

General considerations: Parliament cites serious shortcomings in the responses to issues raised by the Court of Auditors such as: i) the management of procurement procedures, ii) the lack of respect to, and frequent lack of, implementing procedures regarding the identification and management of conflicts of interest for its staff and experts, and iii) the criteria used for recruiting staff.

These could result in:

- persistent errors in the management of procurement procedures,
- potential risks to the independence of experts/staff involved in the evaluation of medicinal products,
- potential deficiencies in staff/experts' recruitment which could not only lead to disqualification of competent candidates but also might have adverse effects on the quality of the Agency?s scientific assessment work.

Budgetary and financial management: as far as the Agency?s management is concerned, Parliament makes the following comments:

- Procurement procedures: Parliament notes serious errors in the procurement procedures corresponding to a significant amount of the Agency's total budget for the financial year of 2009. It notes that the Agency again failed to comply with various requirements of the relevant procurement regulations. It does not accept the Agency?s attempts to justify itself on this point and expects it to improve the quality of its procurement procedures and to draw up a multiannual procurement plan which shall ensure stronger technical and procedural controls. It also invites the Agency to ensure that the results of procurement procedures are checked before contracts are concluded;
- Carryover appropriations: in regard to a carryover of EUR 19.5 million (38% of the Agency's commitments, approximately EUR 14.8 million of which was for activities as yet not implemented or, in some cases, goods not received), Parliament stresses that this situation indicates delays in the implementation of activities financed from the Agency?s budget. It points out that this has also occurred in the past;
- Revenue from fees: Parliament expects the Agency to ensure better coordination between its financial and scientific services in order to remedy the unacceptable, long delay for recovery orders;
- Foreign exchange contracts: Parliament expects the Agency to prudently manage its longstanding policy of entering into a forward foreign exchange contract in order to hedge part of its administrative budget against unfavourable fluctuations in the sterling exchange rate. It expects the Agency to manage such transactions to avoid exchange losses (such as those in 2009 of EUR 900 000). It also calls for an improvement in the Agency?s treasury management;

Performance: Parliament 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; acknowledges that the IAS performed audits and found critical deficiencies in this respect, in particular in the following areas:

- Management of conflicts of interest: Parliament considers it unacceptable that the Agency does not apply the relevant rules effectively, resulting in the fact that there is no guarantee that the evaluation of human medicines is performed by independent experts. It particularly deplores the recruitment of the Agency?s former Executive Director by a consultancy that advises, among others, pharmaceutical companies on developing new medication and reducing the period to their market introduction. In its view, this casts some doubt on the actual independence of the Agency. It considers it unacceptable that the Agency is not complying effectively with its Code of Conduct by setting out principles and guidance on independence and confidentiality applicable to the Management Board and committees' members, experts and Agency's staff. Parliament awaits that the Agency assesses thoroughly, before the allocation of project team leaders to products, whether the interests declared by staff members might influence their impartiality and independence. It urges the Agency, in addition, to document and assess its controls and file the relevant allocation decisions which must be made available on its website. Parliament stresses that the Agency's reputation could be affected in cases where evaluations can be challenged on the grounds of possible conflicts of interest. It urges the Agency to inform the discharge authority of the steps it has taken to ensure the independence of its experts since its inception and wonders why the Court of Auditors? reports since 2006 make no mention of any deficiencies in this respect;
- The Mediator case: on this issue, the plenary asks, in an amendment, to be informed if and how the experts and staff dealing with any of the benfluorex group of drugs were screened on their independence and how their interests declared were verified;
- Procedures supporting the provision of scientific evaluation for human medicines: Parliament considers it unacceptable for the Agency to allow the information in its files on human medicines to be incomplete. It urges the Agency to be more transparent, as well as to

complete and regularly update the European Experts Database;

- Role of the Agency and national competent authorities: Parliament urges the Agency to inform the discharge authority of the terms of its agreement with Member States on the roles and transfer of tasks to national competent authorities when facing subjects such as the independence of committees, experts and the evaluation process, since the agreement came into effect. It considers the Agency responsible for the implementation of pre-existing procedures on the identification and management of conflicts of interest for its experts until this agreement with Member States is fully implemented;
- Human resources management: Parliament calls on the Agency to ensure that sensitive tasks are not assigned to interim staff. It stresses the risks of potential security breaches linked to interim staff's access to sensitive information or lack of awareness by interim staff of the procedure to follow. It calls on the Agency to strengthen its recruitment process and ensure its documentation is correctly managed. It stresses, also, that insufficient documentation in recruitment procedures reduces the possibility for the Agency to respond to allegations of unequal treatment of candidates and/or arbitrary decisions on recruitment of staff;

Internal audit: Parliament considers it unacceptable that the Executive Director's statement of assurance, dated 13 May 2010, does not mention any reservations, and is consequently inconsistent with the undertaking given in the Code of Conduct adopted by the Agency in the light of the statements of assurance from the IAS and the Court of Auditors. It recalls that the Executive Director's report is required to contain a summary of the content of the reports from the IAS to the discharge authority and wonders if these requirements were met in previous years. Parliament calls on the Agency to forward the IAS reports since 2007 to the discharge authority by 30 June 2011. Parliament acknowledges that, out of the 32 recommendations of the IAS, one is ?critical? on the implementing procedures involving experts and twelve are ?very important? mainly on human resources management, on management of staff's conflicts of interest and on other procedures supporting the provision of scientific evaluation for human medicines in the Agency. It calls, therefore, on the Agency to inform the discharge authority about the precise content of these recommendations without delay.

Actions to be taken by the Agency by 30 June 2011: Parliament urges the Agency's Executive Director to undertake a thorough verification of the effective use of the existing procedures regarding the identification and management of conflicts of interest for its staff and experts and to communicate the results to the discharge authority by 30 June 2011. It expects the Governing Board swiftly to adopt an action plan to remedy the shortcomings in the procurement procedures, as well as measures to improve the Agency?s management.

2009 discharge: European Medicines Agency (EMEA)

The Committee on Budgetary Control adopted the second report drafted by Georgios STAVRAKAKIS (S&D, EL) granting he Executive Director of the European Medicines Agency discharge in respect of the implementation of the Agency's budget for the financial year 2009.

This report is the follow up to the postponement of the discharge decision on 11 May 2011.

Stating that the Court of Auditors had reserved its opinion on the legality and reliability of the underlying transactions, Members made a series of recommendations (other than those outlined in the draft resolution as regards the performance, financial management and the controls ? see DEC/2010/2271) which accompanies the decision postponing the discharge.

General considerations: Members acknowledges receipt of a letter of the Chair of the Agency's Management Board of 17 June 2011 in which it is stated that the Agency has taken actions to address the 2009 shortcomings. They regret, however, that not all the information requested was submitted and call on the Agency should continue to inform on a three-monthly basis the discharge authority on the results of the actions requested by the discharge authority.

Members underline that the discharge authority shall 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 IAS. They expect, therefore, the Agency to inform the discharge authority on the actions implemented and their results and to submit the documents requested, especially with regard to the following issues:

- the process of the adoption by the Management Board of the action plan with specific measures and a timetable for implementation to remedy the shortcomings in the procurement procedures;
- the thorough verification of the effective use of the existing procedures regarding the identification and management of conflicts of interest for its staff and experts;
- the submission of the IAS reports according to the Financial Regulation.

Specific comments: Members made the following observations:

Procurement procedures: Members remind the Agency to continue improving the quality of its procurement system and to comply strictly with the requirements of the relevant rules on public procurement, so as to rectify the shortcomings pointed out by the Court of Auditors. Noting the initiation of the actions to develop an action plan on improving procurement procedures, Members call on the Agency to proceed promptly with the adoption of an action plan to remedy the shortcomings in the procurement procedures, in particular the errors in managing contract award procedures, by providing for more rigorous technical and procedural checks, and to inform the discharge authority accordingly. According to the 2009 annual report, the Agency did not carry out enough checks to mitigate the risk of errors on a number of procedures for the procurement of large IT framework contracts.

Carryover appropriations: Members note that the Court of Auditors reported that approximately EUR 14 800 000 of a carryover of EUR 19 500 000 (38 % of the Agency's commitments in 2009) was for activities as yet not implemented (or, in some cases, goods not received for services which may spread across more than one financial year) at the year-end. They remind the Agency therefore to take action in this respect and looks forward to receiving assurance from the Court of Auditors on this.

Foreign-exchange contracts: Members acknowledge the Agency?s commitment to limit its risks due to exchange rate variance and that as of 11 June 2010 it revised its Treasury Policy by: establishing an internal consultation committee to advise the accounting officer on hedging strategies; limiting the hedging to 50 % of estimated requirement; and ensuring that achievable market rates match or are above the budget costing rate.

Management of conflicts of interest: overall Members take note of the Agency's replies on the compliance with its Code of Conduct by setting out principles and guidance on independence and confidentiality applicable to the Management Board and members of committees, experts and the Agency's staff. Members acknowledge the Agency's reply in which it is stated that there is no onus on it to request or monitor the

annual declaration of financial interests of experts responsible for evaluating medicinal products, as this lies with the Member States' competent authorities (Article 126b of Directive 2001/83/EC as amended by Directive 2004/27/EC).

The report stresses that it is not only the Agency's reputation that could be affected in cases where evaluations can be challenged on the grounds of possible conflicts of interest but also that such conflicts of interest do not guarantee the optimal protection of European citizens' health.

Members note that, as of 1 July 2011, the new electronic Declaration of Interests (e-DoI) form went live and all experts were requested to fill in the new e-DoI and that the e-DoIs of all experts included in the Experts database have been made publicly available on the Agency's website as of 30 September 2011. Members insist, but also warn the Agency, that all the actions 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.

Human resources management: lastly, Members welcome the fact that the Agency had stated that it has corrected the deficiencies identified by the IAS for contract agent selection and call on the Agency to keep the discharge authority updated on the level of implementation of these actions.

2009 discharge: European Medicines Agency (EMEA)

PURPOSE: to grant discharge to the European Medicines Agency for the financial year 2009.

NON-LEGISLATIVE ACT: Decision 2011/758/UE of the European Parliament on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2009.

CONTENT: with this Decision the European Parliament grants the Executive Director of the European Medicines Agency discharge in respect of the implementation of the Agencys budget for the financial year 2009.

The Decision is in accordance with Parliaments resolution of 25 October 2011 and includes a series of observations which form an integral part of the Decision refusing discharge (please refer to the summary of 25 October 2011.)

A parallel decision, adopted on the same day, approved the final accounts for this Community Agency for the financial year 2009.

2009 discharge: European Medicines Agency (EMEA)

Following the postponement of the discharge decision in May 2011, the European Parliament adopted a 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 2009. The decision to grant the discharge shall also constitute the closure of the accounts for this Agency.

Furthermore, Parliament adopted a resolution with observations which are an integral part of the decision to grant discharge. These may be summarised as follows:

General assessment:Parliament acknowledges receipt of a letter of the Chair of the Agency's Management Board of 17 June 2011 in which it is stated that the Agency has taken actions to address the 2009 shortcomings. It regrets, however, that not all the information requested was submitted and call on the Agency should continue to inform on a three-monthly basis the discharge authority on the results of the actions requested by the discharge authority.

Parliament underlines that the discharge authority shall 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 IAS. It expects, therefore, the Agency to inform the discharge authority on the actions implemented and their results and to submit the documents requested, especially with regard to the following issues:

- the process of the adoption by the Management Board of the action plan with specific measures and a timetable for implementation to remedy the shortcomings in the procurement procedures;
- the thorough verification of the effective use of the existing procedures regarding the identification and management of conflicts of interest for its staff and experts;
- the submission of the IAS reports according to the Financial Regulation.

Specific observations: Parliament also makes a series of more technical observations in the following areas:

- improving the procurement procedure;
- strengthen technical elements to avoid carry-overs;
- commitment of the Agency to limit risks due to exchange rate variance.

Management of conflicts of interest: overall, Parliament takes note of the Agency's replies on the compliance with its Code of Conduct by setting out principles and guidance on independence and confidentiality applicable to the Management Board and members of committees, experts and the Agency's staff. It acknowledges the Agency's reply in which it is stated that there is no onus on it to request or monitor the annual declaration of financial interests of experts responsible for evaluating medicinal products, as this lies with the Member States' competent authorities (Article 126b of Directive 2001/83/EC as amended by Directive 2004/27/EC).

Parliament calls therefore on the Commission to remind the respective authorities in the Member States of their obligations in this matter.

It stresses that it is not only the Agency's reputation that could be affected in cases where evaluations can be challenged on the grounds of possible conflicts of interest but also that such conflicts of interest do not guarantee the optimal protection of European citizens' health. It recalls that there is also an electronic Declaration of Interests (e-DoI) that all experts were requested to fill.

The resolution calls on the Agency to inform the discharge authority on actions taken on issues relating to the effective compliance with its Code of Conduct as regards the management of conflicts of interest. It insists, but also warns the Agency, that all the actions 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.