



# Procedure file

| Basic information                               |                                |                     |
|---|--------------------------------|---------------------|
| DEC - Discharge procedure                       | <a href="#">2012/2190(DEC)</a> | Procedure completed |
| 2011 discharge: European Medicines Agency (EMA) |                                |                     |
| Subject<br>8.70.03.07 Previous discharges       |                                |                     |

| Key players         |  |   |            |
|---------------------|--|---|------------|
| European Parliament | Committee responsible                                  | Rapporteur  | Appointed  |
|                     | <b>CONT</b> Budgetary Control                          | ALDE <a href="#">GERBRANDY Gerben-Jan</a><br>Shadow rapporteur<br>PPE <a href="#">SARVAMAA Petri</a><br>S&D <a href="#">AYALA SENDER Inés</a><br>Verts/ALE <a href="#">STAES Bart</a><br>ECR <a href="#">BRADBOURN Philip</a><br>EFD <a href="#">ANDREASEN Marta</a><br>NI <a href="#">EHRENHAUSER Martin</a> | 29/02/2012 |
| European Commission | Committee for opinion                                  | Rapporteur for opinion  | Appointed  |
|                     | <b>ENVI</b> Environment, Public Health and Food Safety | S&D <a href="#">HAUG Jutta</a>  | 20/09/2012 |
|                     | Commission DG<br><a href="#">Budget</a>                | Commissioner<br>ŠEMETA Algirdas   |            |

| Key events |  |   |         |
|------------|--|---|---------|
| 24/07/2012 | Non-legislative basic document published   | <a href="#">COM(2012)0436</a>   | Summary |
| 13/09/2012 | Committee referral announced in Parliament |   |         |
| 19/03/2013 | Vote in committee                          |   |         |
| 22/03/2013 | Committee report tabled for plenary        | <a href="#">A7-0098/2013</a>  | Summary |
| 16/04/2013 | Debate in Parliament                       |  |         |
| 17/04/2013 | Results of vote in Parliament              |  |         |
| 17/04/2013 | Decision by Parliament                     | <a href="#">T7-0150/2013</a>  | Summary |
| 17/04/2013 | End of procedure in Parliament             |   |         |
| 16/11/2013 | Final act published in Official Journal    |   |         |

| Technical information |
|-----------------------|
|                       |

|                            |                           |
|----------------------------|---------------------------|
| Procedure reference        | 2012/2190(DEC)            |
| Procedure type             | DEC - Discharge procedure |
| Stage reached in procedure | Procedure completed       |
| Committee dossier          | CONT/7/10520              |

## Documentation gateway

|   |      |  |            |      |         |
|---|------|--|------------|------|---------|
| Non-legislative basic document                      |      | <a href="#">COM(2012)0436</a>                                | 25/07/2012 | EC   | Summary |
| Court of Auditors: opinion, report                  |      | N7-0022/2013<br><a href="#">OJ C 388 15.12.2012, p. 0116</a> | 05/09/2012 | CofA | Summary |
| Committee draft report                              |      | <a href="#">PE497.831</a>                                    | 23/01/2013 | EP   |         |
| Committee opinion                                   | ENVI | <a href="#">PE500.745</a>                                    | 28/01/2013 | EP   |         |
| Document attached to the procedure                  |      | <a href="#">05753/2013</a>                                   | 01/02/2013 | CSL  | Summary |
| Amendments tabled in committee                      |      | <a href="#">PE497.879</a>                                    | 27/02/2013 | EP   |         |
| Committee report tabled for plenary, single reading |      | <a href="#">A7-0098/2013</a>                                 | 22/03/2013 | EP   | Summary |
| Text adopted by Parliament, single reading          |      | <a href="#">T7-0150/2013</a>                                 | 17/04/2013 | EP   | Summary |

## Final act

[Decision 2013/584](#)  
[OJ L 308 16.11.2013, p. 0254](#) Summary

## 2011 discharge: European Medicines Agency (EMA)

**PURPOSE:** presentation by the Commission of the consolidated annual accounts of the European Union for the financial year 2011, as part of the 2011 discharge procedure.

Analysis of the accounts of the European Medicines Agency (EMA).

**CONTENT:** this Commission document sets out the consolidated annual accounts of the European Union for the financial year 2011 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 (EMA).

In 2011, 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;
- the Agency's budget for the 2011 financial year: the Agency's budget for 2011, as presented in the Commission document on the consolidated annual accounts of the European Union, gives the following figures:
  - forecasted income budget: EUR 209 million;
  - entitlements established: EUR 220 million;
  - amounts received: EUR 199 million;
  - outstanding: EUR 21 million.

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/2012/07/WC500129887.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Report/2012/07/WC500129887.pdf)

## 2011 discharge: European Medicines Agency (EMA)

**PURPOSE:** presentation of the EU Court of Auditors report on the annual accounts of the European Medicines Agency for the financial year 2011, 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 Courts opinion, the Agencys Annual Accounts fairly present, in all material respects, its financial position as of 31 December 2011 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 2011 are, in all material respects, legal and regular.

The report confirms that the Agencys 2011 budget amounted to EUR 208.863 million and that the number of staff employed by the Agency at the end of the year was 728.

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:

Courts comments:

- carry-overs: the Court notes again that the level of carry- over is excessive and at odds with the principle of annuality;
- public procurement: the Agency increased in 2011 the financial envelope of an irregular framework contract for IT services concluded in 2009 for which the Court had qualified its opinion on the legality and regularity of the transactions underlying the Agencys 2009 accounts. According to the Court, there is scope for improving the transparency of procurement procedures as regards the justification of the estimated contract volumes and the definition, publication and application of selection criteria;
- recruitment: the Court identified a need to improve the transparency of staff selection procedures.

Agencys replies:

- the Agency states that since 2008 it has made every effort to reduce its level of carry-over to an acceptable level. It has in fact achieved a continuous reduction. As the operations of the Agency are of a multi-annual nature and not linked to the calendar year, a certain level of carry-overs is unavoidable;
- the Agency considers that the IT framework contract was not irregular. As a consequence, the extension of the framework contract is considered not irregular as well;
- the Agency has taken note of the Courts comments and updated its procedures with a view to transparency and timely documentation.

Lastly, the Court of Auditors report contains a summary of the Agencys activities in 2011. This is focused on the following:

- applications for marketing authorisations for 100 medicines for human use ;
- pharmacovigilance activities;
- mutual recognition procedures and decentralised procedures: started 6 401; (6 715 ended positively);
- scientific advice;
- applications for paediatric investigation plans: 187 relating to 220 indications;
- applications for marketing authorisations for 11 medicinal products for veterinary use;
- 449 inspections;
- herbal medicinal products;
- 166 applications for orphan medicinal products (111 favourable opinions);
- requests for SME status: 433 requests and 350 applications for fee reduction or deferrals.

## 2011 discharge: European Medicines Agency (EMA)

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The Committee on Budgetary Control adopted the report by Gerben-Jan GERBRANDY (ADLE, NL) on 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 2011.

Noting that the Court of Auditors stated that it has obtained reasonable assurances that the annual accounts of the Agency for the financial year 2011 are reliable and that the underlying transactions are legal and regular, Members approve the closure of the Agencys accounts. However, they make a number of recommendations that need 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](#):

- Financing, budget and financial management: Members recall that the Agency's budget for 2011 was EUR 208 863 000, which represents a nominal increase over the financial year 2010. They recall that the total Union contributions amounted to EUR 39 765 191.39 for 2011, which represents an 8.65% increase compared to the previous year and that the rest was financed by fees paid by the pharmaceutical industry when applying for, obtaining or maintaining Union marketing authorisations. Members state that a large amount of the Agency's revenue is estimated to have derived from the fee revenue, which continues to increase year on year. Members are concerned as regards the need to introduce a system of remuneration for services provided by Member States authorities, based on their real costs.
- Implementation rate of appropriations: Members observe that in terms of committed and paid appropriations, the Agency's execution rate stands at 95.21% and 81.97% respectively. They call on the Agency to continue its efforts to improve its execution rate of payment. They are concerned that once again, the Court of Auditors reported that payment appropriations for Title II ("Administrative expenditure") have been carried over to 2012, representing 29% of the budget which is excessive and at odds with the principle of annuality.
- Conflicts of interest: noting the problems as regards the conflict of interest in the light of the previous discharge procedure, Members welcome the efforts made but state that the Agency did not adequately manage conflict of interest situations. They welcome the Agency's commitment to undertake in the first half of 2013 a review of the implementation of its revised policy on the handling of

conflicts of interests and that an ex ante and ex post check on the handling of conflicts of interests is currently being developed for implementation in the second quarter of 2013. The Agency is called upon to keep the discharge authority informed on their respective outcomes.

Lastly, Members made a series of observations concerning the recruitment and procurement procedures and controls carried out by this Community Agency.

## 2011 discharge: European Medicines Agency (EMA)

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The European Parliament adopted a decision on 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 2011. The vote on the decision to grant discharge covers the closure of the accounts (in accordance with Annex VI, Article 5(1) of the European Parliaments Rules of Procedure).

Noting that the Court of Auditors stated that it has obtained reasonable assurances that the annual accounts of the Agency for the financial year 2011 are reliable and that the underlying transactions are legal and regular, Parliament adopted a resolution containing a number of recommendations that need 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](#):

- Financing, budget and financial management: Parliament recalls that the Agency's budget for 2011 was EUR 208 863 000, which represents a nominal increase over the financial year 2010. It recalls that the total Union contributions amounted to EUR 39 765 191.39 for 2011, which represents an 8.65% increase compared to the previous year and that the rest was financed by fees paid by the pharmaceutical industry when applying for, obtaining or maintaining Union marketing authorisations. Members state that a large amount of the Agency's revenue is estimated to have derived from the fee revenue, which continues to increase year on year. Members are concerned as regards the need to introduce a system of remuneration for services provided by Member States authorities, based on their real costs.
- Implementation rate of appropriations: Parliament observes that in terms of committed and paid appropriations, the Agency's execution rate stands at 95.21% and 81.97% respectively. It calls on the Agency to continue its efforts to improve its execution rate of payment. It is concerned that once again, the Court of Auditors reported that payment appropriations for Title II ("Administrative expenditure") have been carried over to 2012, representing 29% of the budget which is excessive and at odds with the principle of annuality.
- Recruitment procedures: Parliament states the lack of transparency in the staff selection procedures. It states that there was no evidence of any action taken to address the issues.
- Conflicts of interest: noting the problems as regards the conflict of interest in the light of the previous discharge procedure, Parliament welcomes the efforts made but state that the Agency did not adequately manage conflict of interest situations. It welcomes the Agency's commitment to undertake in the first half of 2013 a review of the implementation of its revised policy on the handling of conflicts of interests and that an ex ante and ex post check on the handling of conflicts of interests is currently being developed for implementation in the second quarter of 2013. The Agency is called upon to keep the discharge authority informed on their respective outcomes.

Lastly, Parliament made a series of observations concerning the procurement procedures and controls carried out by this Community Agency.

## 2011 discharge: European Medicines Agency (EMA)

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PURPOSE: to grant discharge to the European Medicines Agency (EMA) for the financial year 2011.

NON-LEGISLATIVE ACT: Decision 2013/584/EU of the European Parliament on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2011.

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 Agency's budget for 2011.

The Decision is consistent with the European Parliaments resolution adopted on 17 April 2013 and includes a series of observations that form an integral part of the discharge decision (refer to the summary of the opinion of 17 April 2013).

Decision 2013/585/EU, adopted on the same day, approves the closure of the accounts for this Community agency for 2011.