



2015/2171(DEC)

4.3.2016

AMENDMENTS

1 - 16

Draft report
Derek Vaughan
(PE569.754v02-00)

on discharge in respect of the implementation of the budget of the European
Medicines Agency for the financial year 2014
(2015/2171(DEC))

AM_Com_NonLegReport

Amendment 1
Anders Primdahl Vistisen

Proposal for a decision 1
Paragraph 1

Proposal for a decision

1. **Grants** the Executive Director of the European Medicines Agency discharge in respect of the implementation of the Agency's budget for the financial year 2014;

Amendment

1. **Postpones 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 2014;

Or. en

Amendment 2
Ryszard Czarnecki, Raffaele Fitto, Beata Gosiewska, Richard Sulík

Proposal for a decision 1
Paragraph 1

Proposal for a decision

1. **Grants** the Executive Director of the European Medicines Agency discharge in respect of the implementation of the Agency's budget for the financial year 2014;

Amendment

1. **Postpones 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 2014;

Or. en

Amendment 3
Anders Primdahl Vistisen

Proposal for a decision 2
Paragraph 2

Proposal for a decision

2. **Approves** the closure of the accounts of the European Medicines Agency for the financial year 2014;

Amendment

2. **Postpones** the closure of the accounts of the European Medicines Agency for the financial year 2014;

Amendment 4

Ryszard Czarnecki, Raffaele Fitto, Beata Gosiewska, Richard Sulík

Proposal for a decision 2

Paragraph 2

Proposal for a decision

2. ***Approves*** the closure of the accounts of the European Medicines Agency for the financial year 2014;

Amendment

2. ***Postpones*** the closure of the accounts of the European Medicines Agency for the financial year 2014;

Or. en

Amendment 5

Benedek Jávor

Motion for a resolution

Paragraph 2

Motion for a resolution

2. Notes from the Court's report that the Agency's Fee Regulation¹³ provides due dates for the collection of fees from applicants and the Agency's related payments to national competent authorities; notes that these due dates were not respected for most of the transactions audited by the Court; ascertains from the Agency that it has redesigned and streamlined its main operational processes including financial authorisations and fee collections; takes note that the further automation of these processes was planned to be implemented by the Agency by the end of 2015; calls on the Agency to report to the discharge authority on measures implemented to remedy this issue;

Amendment

2. Notes from the Court's report that the Agency's Fee Regulation¹³ provides due dates for the collection of fees from applicants and the Agency's related payments to national competent authorities; notes that these due dates were not respected for most of the transactions audited by the Court; ascertains from the Agency that it has redesigned and streamlined its main operational processes including financial authorisations and fee collections; takes note that the further automation of these processes was planned to be implemented by the Agency by the end of 2015; calls on the Agency to ***take all further steps needed in order to ensure that its pharmacovigilance responsibilities are fully met and to effectively*** report to the discharge authority on measures implemented to remedy this issue;

¹³ Article 10(1) and 11(1) of Regulation (EC) No 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products.

¹³ Article 10(1) and 11(1) of Regulation (EC) No 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products.

Or. en

Amendment 6
Barbara Kappel

Motion for a resolution
Paragraph 3

Motion for a resolution

3. Notes that budget monitoring efforts during the financial year 2014 resulted in a budget implementation rate of 94,32 %, representing a decrease of 2,44 % compared with the previous year; notes furthermore that the payment appropriations execution rate was at 82,30 %, representing a decrease of 3,98 %;

Amendment

3. Notes that budget monitoring efforts during the financial year 2014 resulted in a budget implementation rate of 94,32 %; ***regrets, however that this represents*** a decrease of 2,44 % compared with the previous year; notes furthermore that the payment appropriations execution rate was at 82,30 %; ***regrets that, here again, this represents*** a decrease of 3,98 %;

Or. de

Amendment 7
Barbara Kappel

Motion for a resolution
Paragraph 5 a (new)

Motion for a resolution

5a. Calls on the Agency as far as possible to reduce the level of committed appropriations carried over in the future in order to strengthen transparency and accountability;

Or. de

Amendment 8
Barbara Kappel

Motion for a resolution
Paragraph 7

Motion for a resolution

7. Takes note from the Agency that, in order to increase the level of human resources allocated to operational tasks, it is further improving its recruitment and resource planning procedures; ascertains from the Court's Report that in 2014 the Agency concluded an EUR 15 000 000 framework contract for high-level management consultancy services covering the 2014-2017 period; notes that the objectives and activities to be carried out were not sufficiently specific to justify the procurement decision or the volume of the contract; notes furthermore that the Court found no evidence that the Agency's Management Board had been consulted on the procurement decision; acknowledges from the Agency that consulting its Management Board in this case was not required by the financial rules;;

Amendment

7. Takes note from the Agency that, in order to increase the level of human resources allocated to operational tasks, it is further improving its recruitment and resource planning procedures; ascertains from the Court's Report that in 2014 the Agency concluded an EUR 15 000 000 framework contract for high-level management consultancy services covering the 2014-2017 period; notes that the objectives and activities to be carried out were not sufficiently specific to justify the procurement decision or the volume of the contract; ***calls on the Agency therefore, in the interests of transparency and accountability, to ensure that the objectives and activities to be carried out are in fact specified***; notes furthermore that the Court found no evidence that the Agency's Management Board had been consulted on the procurement decision; acknowledges from the Agency that consulting its Management Board in this case was not required by the financial rules;

Or. de

Amendment 9
Tamás Deutsch

Motion for a resolution
Paragraph 7 a (new)

Motion for a resolution

Amendment

7a. Asks the EU institutions and bodies to

apply strictly the measures pertaining to discretion and exclusion in respect of public procurement, with proper background checks being carried out in every instance, and to apply the exclusion criteria in order to debar companies in the event of any conflict of interest, this being essential to protect the EU's financial interests;

Or. en

Amendment 10
Tamás Deutsch

Motion for a resolution
Paragraph 8 a (new)

Motion for a resolution

Amendment

8a. Encourages the EU institutions and agencies to better raise awareness of the conflict-of-interest policy among their officials, alongside ongoing awareness-raising activities and the inclusion of integrity and transparency as an obligatory item to be discussed during recruitment procedures and performance reviews; considers that a distinction should be made between elected representatives and public officials in the legislation on conflicts of interest; believes that there should also be such regulations in the Member States for public officials and civil servants involved in the administration and monitoring of EU subsidies; calls on the Commission to submit a draft legal basis on this matter;

Or. en

Amendment 11
Tamás Deutsch

Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution

Amendment

11a. Calls for an overall improvement in the prevention of, and the fight against, corruption in the public sector, and especially within the EU institutions and agencies, through a holistic approach, commencing with better public access to documents and more stringent rules on conflicts of interest, the introduction or strengthening of transparency registers and the provision of sufficient resources for law enforcement measures, and also through improved cooperation among Member States and with relevant third countries;

Or. en

Amendment 12
Tamás Deutsch

Motion for a resolution
Paragraph 11 b (new)

Motion for a resolution

Amendment

11b. Calls on all the EU institutions and agencies to enhance their procedures and practices aimed at safeguarding the financial interests of the Union and to actively contribute to a results-oriented discharge process;

Or. en

Amendment 13
Benedek Jávor

Motion for a resolution
Paragraph 12 a (new)

Motion for a resolution

Amendment

12a. Is extremely concerned that despite the identified weakness in the functioning of pharmacovigilance, the Agency launched in March 2014 a pilot project on adaptive licencing - endorsed neither by the Parliament nor by the Council, as implementing adaptive pathways would shift the burden of evidence from pre-marketing to post-marketing, leading to a situation where premature marketing authorisations could become the rule;

Or. en

Amendment 14
Tamás Deutsch

Motion for a resolution
Paragraph 12 a (new)

Motion for a resolution

Amendment

12a. Demands that all those EU institutions and agencies that have not yet done so urgently adopt internal rules on whistleblowing and take a common approach to their obligations, focusing on the protection of whistleblowers; requests special attention for the protection of whistleblowers in the context of the Directive on the Protection of Trade Secrets; calls on the Commission to promote legislation on a minimum level of protection for whistleblowers in the EU; calls on the institutions and agencies to amend the Staff Regulations to ensure that they not only formally oblige officials to report irregularities of all kinds but also lay down adequate protection for whistleblowers; calls on the institutions and agencies to implement Article 22(c) of the Staff Regulations without delay;

Or. en

Amendment 15
Derek Vaughan

Motion for a resolution
Paragraph 13

Motion for a resolution

13. Takes note that in 2014, the Agency carried out an administrative procedure **against** its Information, Communication and Technology (ICT) **manager**; notes that significant weaknesses in management control were reported, implying considerable operational and financial risks to the Agency; notes from the Agency that no considerable financial risks were reported in the administrative enquiry to the Agency's Executive Director; observes that an action plan to address the issue was established and implemented; calls on the Agency to report to the discharge authority on the effectiveness of the measures taken after they have been evaluated;

Amendment

13. Takes note that in 2014, the Agency carried out an administrative procedure **with respect to** its Information, Communication and Technology (ICT) **Division**; notes that significant weaknesses in management control were reported, implying considerable operational and financial risks to the Agency; notes from the Agency that no considerable financial risks were reported in the administrative enquiry to the Agency's Executive Director; observes that an action plan to address the issue was established and implemented; calls on the Agency to report to the discharge authority on the effectiveness of the measures taken after they have been evaluated;

Or. en

Amendment 16
Giovanni La Via

Motion for a resolution
Paragraph 13

Motion for a resolution

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Amendment

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Or. en