



EUROPEAN PARLIAMENT

2014 - 2019

---

*Committee on Budgetary Control*

---

**2014/2102(DEC)**

6.3.2015

# **AMENDMENTS**

## **1 - 18**

**Draft report**  
**Ryszard Czarnecki**  
(PE539.704v01-00)

on the discharge in respect of the implementation of the budget of the  
European Medicines Agency for the financial year 2013  
(2014/2102(DEC))

AM\_Com\_NonLegReport

**Amendment 1**  
**Monica Macovei**

**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 2013 / *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 2013;*

*Amendment*

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 2013;

Or. en

**Amendment 2**  
**Tomáš Zdechovský**

**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 2013 / *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 2013;*

*Amendment*

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 2013;

Or. en

**Amendment 3**  
**Richard Ashworth, 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 2013*** / 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 2013;

*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 2013;

Or. en

**Amendment 4**  
**Tomáš Zdechovský**

**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 2013 / ***Postpones the closure of the accounts of the European Medicines Agency for the financial year 2013;***

*Amendment*

2. Approves the closure of the accounts of the European Medicines Agency for the financial year 2013;

Or. en

**Amendment 5**  
**Richard Ashworth, 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***

*Amendment*

2. Postpones the closure of the accounts of the European Medicines Agency for the

*financial year 2013* / Postpones the closure of the accounts of the European Medicines Agency for the financial year 2013;

financial year 2013;

Or. en

**Amendment 6**  
**Tomáš Zdechovský**

**Motion for a resolution**  
**Paragraph 2 – indent 3**

*Motion for a resolution*

– in order to improve its communication with Union citizens, the Agency has recently implemented several initiatives such as publication of strategic documents including summaries for the public, meeting highlights, newsletters or annual reports; notes furthermore in this regard the development of IT communication tools such as ‘Public health communication’ which provides the public with key information on medicines, mainly on their safety;

*Amendment*

– in order to improve its communication with Union citizens, the Agency has recently implemented several initiatives such as publication of strategic documents including summaries for the public, meeting highlights, newsletters or annual reports; notes furthermore in this regard the development of IT communication tools such as ‘Public health communication’ which provides the public with key information on medicines, mainly on their safety; ***in this regard encourages the Agency to set the pharmacovigilance public hearings;***

Or. en

**Amendment 7**  
**Tomáš Zdechovský**

**Motion for a resolution**  
**Paragraph 3 a (new)**

*Motion for a resolution*

*Amendment*

***3 a. Notes that 83% of Agency’s budget comes from the industry fees, representing gradual increase; requires complete transparency about this aspect of budget to avoid any risks for***

*consumers' rights or Agency's reputation;*

Or. en

**Amendment 8**  
**Tomáš Zdechovský**

**Motion for a resolution**  
**Paragraph 6 a (new)**

*Motion for a resolution*

*Amendment*

***6 a. Notes that the Agency faced some controversy regarding several cases of recruitment procedures in the past; calls on the Agency to always ensure complete transparency and clarification with regard to the recruitment procedures;***

Or. en

**Amendment 9**  
**Benedek Jávor**

**Motion for a resolution**  
**Paragraph 7**

*Motion for a resolution*

*Amendment*

7. Acknowledges from the Agency that the transparency criteria for partner, patient, healthcare and consumer organisations has been revised during 2014 in order to increase the transparency of funding; notes the adoption of the document with detailed criteria regarding the evaluation of financial information from patients, consumers and healthcare professionals organisations; notes furthermore that this document is used for assessing the organisations' eligibility to participate in the dialogue with the Agency; recalls that the document also states that the organisations have to declare any conflict

7. Acknowledges from the Agency that the transparency criteria for partner, patient, healthcare and consumer organisations has been revised during 2014 in order to increase the transparency of funding; notes the adoption of the document with detailed criteria regarding the evaluation of financial information from patients, consumers and healthcare professionals organisations; notes furthermore that this document is used for assessing the organisations' eligibility to participate in the dialogue with the Agency; recalls that the document also states that the organisations have to declare any conflict

of interests at the start of the meetings through which the dialogue is commenced;

of interests at the start of the meetings through which the dialogue is commenced; *notes with regret the reduction of cool-off periods from 5 to 3 years; furthermore, notes with regret that the arbitrary distinction between direct and indirect conflicts of interest has been kept;*

Or. en

**Amendment 10**  
**Tomáš Zdechovský**

**Motion for a resolution**  
**Paragraph 7**

*Motion for a resolution*

7. Acknowledges from the Agency that the transparency criteria for partner, patient, healthcare and consumer organisations has been revised during 2014 in order to increase the transparency of funding; notes the adoption of the document with detailed criteria regarding the evaluation of financial information from patients, consumers and healthcare professionals organisations; notes furthermore that this document is used for assessing the organisations' eligibility to participate in the dialogue with the Agency; recalls that the document also states that the organisations have to declare any conflict of interests at the start of the meetings through which the dialogue is commenced;

*Amendment*

7. Acknowledges from the Agency that the transparency criteria for partner, patient, healthcare and consumer organisations has been revised during 2014 in order to increase the transparency of funding; notes the adoption of the document with detailed criteria regarding the evaluation of financial information from patients, consumers and healthcare professionals organisations; notes furthermore that this document is used for assessing the organisations' eligibility to participate in the dialogue with the Agency; recalls that the document also states that the organisations have to declare any conflict of interests at the start of the meetings through which the dialogue is commenced; *further calls on the Agency to introduce a list of the patients' organizations it is working with and to place it on its website, linking it to the funding sources of these organizations in order to enhance transparency;*

Or. en

**Amendment 11**  
**Monica Macovei**

**Motion for a resolution**  
**Paragraph 7 a (new)**

*Motion for a resolution*

*Amendment*

***7 a. Acknowledges that the Agency complied with the recommendation of the discharge authority to devote a specific part of its Annual Activity Report on the prevention and management of conflict of interests;***

Or. en

**Amendment 12**  
**Tomáš Zdechovský**

**Motion for a resolution**  
**Paragraph 8**

*Motion for a resolution*

*Amendment*

8. Notes that the Agency's Management Board has endorsed ***the*** revised ***the*** policy on ***the*** handling of declarations of interests of members of scientific committees and experts; notes that the electronic declaration of interests form and the procedural guidance were to be finalised during 2014; calls on the Agency to inform the discharge authority on the outcomes as soon as they are available;

8. Notes that the Agency's Management Board has endorsed ***a*** revised policy on handling of declarations of interests of members of scientific committees and experts; ***regrets that the main loopholes, such as distinction between direct and indirect conflicts of interest, prevail, while the Agency takes into account mainly only direct conflict of interest;*** notes that the electronic declaration of interests form and the procedural guidance were to be finalised during 2014; calls on the Agency to inform the discharge authority on the outcomes as soon as they are available;

Or. en

**Amendment 13**  
**Monica Macovei**



**Motion for a resolution**  
**Paragraph 8 a (new)**

*Motion for a resolution*

*Amendment*

**8 a. Notes with satisfaction that this policy entered into force on 30.01.2015;**

Or. en

**Amendment 14**  
**Monica Macovei**

**Motion for a resolution**  
**Paragraph 8 b (new)**

*Motion for a resolution*

*Amendment*

**8 b. Welcomes that the revised policy includes a better distinction of the declared interest: a person with an executive or leading role in the development of a medicine during a previous employment has a lifetime bar of non-involvement with the concerned company or product. For the majority of declared interests, a three-year cooling-off period is foreseen;**

Or. en

**Amendment 15**  
**Benedek Jávor**

**Motion for a resolution**  
**Paragraph 8 c (new)**

*Motion for a resolution*

*Amendment*

**8 c. Notes with regret the Agency's understanding of what constitutes commercial confidential information (CCI) is far too broad and**

*includes companies to redact key data about the trial design, methods, and calls on the Agency to properly implement the provisions of the Clinical Trials Regulation (EU) No 536/2014 especially with regard to clinical trial data not to be considered CCI;*

Or. en

**Amendment 16**  
**Tomáš Zdechovský**

**Motion for a resolution**  
**Paragraph 8 d (new)**

*Motion for a resolution*

*Amendment*

*8 d. Regrets that the policies on proactive publication of clinical trial data recently adopted by the Agency go against the transparent provisions of the Clinical Trials Regulation endorsed by the European Parliament by allowing companies to redact data based on potential jeopardy of commercial interests; calls on the Agency to report to the discharge Authority on this issue;*

Or. en

**Amendment 17**  
**Benedek Jávor**

**Motion for a resolution**  
**Paragraph 8 e (new)**

*Motion for a resolution*

*Amendment*

*8 e. Calls on the Agency to publish on its website detailed reports of the scientific advice provided by the Agency to pharmaceutical companies during the drug development and pre-registration*

*process at the time of trial authorization and in any case not later than 12 months after the end of the trial; notes that advice provided by regulators to companies on drug development and pre-registration plans cannot be considered commercially confidential information since there is an overriding public interest in disclosure;*

Or. en

**Amendment 18**  
**Zigmantas Bal ytis**

**Motion for a resolution**  
**Paragraph 9 a (new)**

*Motion for a resolution*

*Amendment*

*9 a. Takes note that the Agency has adopted a set of internal-control standards (ICS) which are intended to guarantee a consistent level of internal control of all business activities throughout the Agency, and define the management rules that all services must follow in their management of resources;*

Or. en