



EUROPEAN PARLIAMENT

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*Committee on the Environment, Public Health and Food Safety*

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**2012/2190(DEC)**

20.12.2012

# **AMENDMENTS**

## **1 - 11**

**Draft opinion**

**Jutta Haug**

(PE500.745v01-00)

on discharge in respect of the implementation of the budget of the European  
Medicines Agency for the financial year 2011  
(2012/2190(DEC))

AM\_Com\_NonLegOpinion

**Amendment 1**  
**José Manuel Fernandes**

**Draft opinion**  
**Paragraph 1 a (new)**

*Motion for a resolution*

*Amendment*

***1a. Points to the role of the European Medicines Agency in protecting and promoting public and animal health by assessing and supervising medicines for human or veterinary use;***

Or. pt

**Amendment 2**  
**Marina Yannakoudakis, Anna Rosbach**

**Draft opinion**  
**Paragraph 1 a (new)**

*Motion for a resolution*

*Amendment*

***1a. Draws attention to the Health and Consumer Protection Commissioner's pledge to pursue an initiative for a common rulebook governing the auditing and management of the Agency and to tackle the various instances of conflicts for interest, whilst examining the scope for cuts to its operating budget;***

Or. en

**Amendment 3**  
**Corinne Lepage, Antonyia Parvanova**

**Draft opinion**  
**Paragraph 2**

*Motion for a resolution*

2. Thinks it is noteworthy in this context that the special report on Conflict of Interests by the Court of Auditors is not taking into account to the full the latest developments and improvements put in place by the Agency; therefore, notes with satisfaction the improvement of all procedures related to transparency and possible conflicts of interest in the Agency and will support the Executive Director in *its* further efforts;

*Amendment*

2. Thinks it is noteworthy in this context that the special report on Conflict of Interests by the Court of Auditors ***concluded that none of the agencies scrutinised, including the EMA, dealt properly with conflicts of interest; notes that the report*** is not taking into account to the full the latest developments and improvements put in place by the Agency; therefore, notes with satisfaction the improvement of all procedures related to transparency and possible conflicts of interest in the Agency; ***intends to ascertain that those procedures are in fact being implemented, especially as regards ex ante and ex post checks on declarations of interests,*** and will support the Executive Director in *his* further efforts;

Or. fr

**Amendment 4**  
**Andrea Zanoni**

**Draft opinion**  
**Paragraph 2**

*Motion for a resolution*

2. Thinks it is noteworthy in this context that the special report on Conflict of Interests by the Court of Auditors is not taking into account to the full the latest developments and improvements put in place by the Agency; therefore, notes with satisfaction the improvement of all procedures related to transparency and possible conflicts of interest in the Agency and will support the Executive Director in *its* further efforts;

*Amendment*

2. Thinks it is noteworthy in this context that the special report on Conflict of Interests by the Court of Auditors is not taking into account to the full the latest developments and improvements put in place by the Agency; therefore, notes with satisfaction the improvement of all procedures related to transparency and possible conflicts of interest in the Agency, ***recalls, however, the importance of continuously working for strengthening and enhancement of all policies related to transparency and independence*** and will support the Executive Director in *his*

further efforts;

Or. en

## **Amendment 5**

**Marina Yannakoudakis, Anna Rosbach**

### **Draft opinion**

#### **Paragraph 2**

##### *Motion for a resolution*

2. Thinks it is noteworthy in this context that the special report on Conflict of Interests by the Court of Auditors is not taking into account to the full the latest developments and improvements put in place by the Agency; therefore, notes ***with satisfaction*** the improvement of all procedures related to transparency and possible conflicts of interest in the Agency and will support the Executive Director in *its* further efforts;

##### *Amendment*

2. Thinks it is noteworthy in this context that the special report on Conflict of Interests by the Court of Auditors is not taking into account to the full the latest developments and improvements put in place by the Agency; therefore, notes the improvement of all procedures related to transparency and possible conflicts of interest in the Agency and will support the Executive Director in *his* further efforts;

Or. en

## **Amendment 6**

**Corinne Lepage, Antonyia Parvanova**

### **Draft opinion**

#### **Paragraph 2 a (new)**

##### *Motion for a resolution*

##### *Amendment*

***2a. Looks to the Agency to produce a report on the implementation of the system of ex ante and ex post verification of declarations of interests; shares the view of the Agency's Executive Director that, given its scope, a system of that kind is beyond the Agency's capacity and remit; believes, therefore, that one option to consider should be a legislative initiative whereby holders of a marketing***

*authorisation (MA) for a pharmaceutical product would be obliged to publish agreements and all benefits in cash or in kind that they provided, directly or indirectly, to experts or bodies with whom they worked;*

Or. fr

#### **Amendment 7**

**Marina Yannakoudakis, Anna Rosbach**

#### **Draft opinion**

#### **Paragraph 7**

##### *Motion for a resolution*

7. Acknowledges the efforts by the executive level of the Agency to encourage a decision by the Management Board to revise the system of remuneration of Member States services based on real costs; ***is fully aware of*** the fact that ***the little*** progress is due to the lack of any decision in the Management Board; welcomes therefore the approach by the Agency's administration to call upon the European Commission for further assistance in this matter;

##### *Amendment*

7. Acknowledges the efforts by the executive level of the Agency to encourage a decision by the Management Board to revise the system of remuneration of Member States services based on real costs; ***deplores*** the fact that ***its limited*** progress is due to the lack of any decision in the Management Board; welcomes therefore the approach by the Agency's administration to call upon the European Commission for further assistance in this matter;

Or. en

#### **Amendment 8**

**Marina Yannakoudakis**

#### **Draft opinion**

#### **Paragraph 8**

##### *Motion for a resolution*

***8. Has no evidence that the Agency has implemented its budget in a non-cost-effective way and has no indication of fraud or irregularities; recommends, on***

##### *Amendment*

***deleted***

*the basis of the facts available, that discharge be granted to the Executive Director of the European Medicines Agency in respect of the implementation of the Agency's budget for the financial year 2011.*

Or. en

**Amendment 9**  
**José Manuel Fernandes**

**Draft opinion**  
**Paragraph 8**

*Motion for a resolution*

**8. *Has no evidence that the Agency has implemented its budget in a non-cost-effective way and has no indication of fraud or irregularities;*** recommends, on the basis of the facts available, that discharge be granted to the Executive Director of the European Medicines Agency in respect of the implementation of the Agency's budget for the financial year 2011.

*Amendment*

8. Recommends, on the basis of the facts available, that discharge be granted to the Executive Director of the European Medicines Agency in respect of the implementation of the Agency's budget for the financial year 2011.

Or. pt

**Amendment 10**  
**Marina Yannakoudakis, Anna Rosbach**

**Draft opinion**  
**Paragraph 8 a (new)**

*Motion for a resolution*

**8a. *Believes that the discharge decision for the Agency should be based upon OECD guidelines to ensure high-quality internationally recognised accounting, audit and financial disclosure standards; invites the European institutions to***

*Amendment*

*incorporate and commit to introducing  
OECD guidelines within a common  
working framework for all European  
institutions and bodies;*

Or. en

**Amendment 11**  
**Marina Yannakoudakis**

**Draft opinion**  
**Paragraph 8 b (new)**

*Motion for a resolution*

*Amendment*

*8b. Is of the opinion that the Agency  
should not be granted discharge in respect  
of the implementation of the Agency  
budget for the financial year 2011 until  
the general budget of the European  
Union is given an unqualified statement  
of assurance by the Court of Auditors.*

Or. en