



**2017/2154(DEC)**

2.3.2018

# **AMENDMENTS**

## **1 - 23**

**Draft report**

**Bart Staes**

2016 discharge: European Medicines Agency (EMA)  
(2017/2154(DEC))



## **Amendment 1**

**Bart Staes**

on behalf of the Verts/ALE Group

### **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 2016 / *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 2016;*

##### *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 2016;

Or. en

## **Amendment 2**

**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 2016 / *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 2016;*

##### *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 2016;

Or. en

## **Amendment 3**

**Ryszard Czarnecki, Notis Marias, 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 2016*** / 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 2016;

*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 2016;

Or. en

**Amendment 4**

**Bart Staes**

on behalf of the Verts/ALE Group

**Proposal for a decision 2**

**Paragraph 1**

*Proposal for a decision*

1. Approves the closure of the accounts of the European Medicines Agency for the financial year 2016 / ***Postpones the closure of the accounts of the European Medicines Agency for the financial year 2016;***

*Amendment*

1. Approves the closure of the accounts of the European Medicines Agency for the financial year 2016;

Or. en

**Amendment 5**

**Bart Staes**

on behalf of the Verts/ALE Group

**Motion for a resolution**

**Paragraph 2**

*Motion for a resolution*

2. Notes that, according to the Court's report, since the introduction of a new IT accounting system in 2011, reporting on commitment workflow and consumption

*Amendment*

2. Notes that, according to the Court's report, since the introduction of a new IT accounting system in 2011, reporting on commitment workflow and consumption

has not been sufficiently transparent; regrets that, although the matter was repeatedly raised with the Agency, no corrective action has been taken; calls on the Agency to implement corrective actions as soon as possible in 2018 and to report to the discharge authority on their implementation;

has not been sufficiently transparent; regrets that, although the matter was repeatedly raised with the Agency, no corrective action has been taken; *take note of the Agency's explanation that "[the Agency] is currently working to increase the reporting functionality of its financial system, in line with the recommendations by the Court"*; calls on the Agency to implement corrective actions as soon as possible in 2018 and to report to the discharge authority on their implementation;

Or. en

## **Amendment 6**

### **Petri Sarvamaa**

#### **Motion for a resolution**

#### **Paragraph 3**

##### *Motion for a resolution*

3. Notes that, according to the Court's report, the Agency concluded corporate rate agreements for the provision of accommodation for experts with 25 hotels in London without using a competitive procurement procedure; notes that for six hotels, payments made in 2016 were above the Financial Regulation's threshold for which an open or restricted competitive procurement procedure is required; **notes with concern** that the six corporate rate agreements and the related 2016 payments, amounting to some EUR 2 100 000 are therefore irregular; notes that, according to the Agency's reply, it will identify and implement a solution for hotel bookings during 2017-2018; calls on the Agency to report to the discharge authority on the implementation of that solution;

##### *Amendment*

3. Notes **with concern** that, according to the Court's report, the Agency concluded corporate rate agreements for the provision of accommodation for experts with 25 hotels in London without using a competitive procurement procedure; notes that for six hotels, payments made in 2016 were above the Financial Regulation's threshold for which an open or restricted competitive procurement procedure is required; **regrets** that the six corporate rate agreements and the related 2016 payments, amounting to some EUR 2 100 000 are therefore irregular; notes that, according to the Agency's reply, it will identify and implement a solution for hotel bookings during 2017-2018; calls on the Agency to report to the discharge authority on the implementation of that solution;

Or. en

**Amendment 7**  
**Petri Sarvamaa**

**Motion for a resolution**  
**Paragraph 9**

*Motion for a resolution*

9. Regrets that, as regards the number of posts occupied on 31 December 2016 for all staff (including contract agents), gender balance ***has not been met, since the*** ratio ***is*** 69 % female to 31 % male; notes however that 14 out of 29 (48%) of the Agency's senior management staff are female; calls on the Agency to take the gender balance issue into account when recruiting new staff and inform the discharge authority in the next discharge procedure of the progress made at the end of the calendar ***years of 2017 and 2018***;

*Amendment*

9. Regrets that, as regards the number of posts occupied on 31 December 2016 for all staff (including contract agents), gender balance ratio ***was*** 69 % female to 31 % male; notes however that 14 out of 29 (48%) of the Agency's senior management staff are female; calls on the Agency to take the gender balance issue into account when recruiting new staff and inform the discharge authority in the next discharge procedure of the progress made at the end of the calendar ***year 2017***;

Or. en

**Amendment 8**  
**Bart Staes**  
on behalf of the Verts/ALE Group

**Motion for a resolution**  
**Paragraph 14**

*Motion for a resolution*

14. Notes that, according to the Court's report, since 2014 the Agency has undergone two major re-organisations including the internal re-allocation of top and middle management positions; notes moreover that the re-allocation of key staff in the area of IT and administration was not successful, causing material risk of instability to the Agency and its operations; notes however that the Agency considers that no instability was suffered by the Agency due to organisational changes; notes moreover that there is no system in place to analyse skills availability, identify gaps and to recruit and allocate appropriate staff; calls on the Agency to pay extra

*Amendment*

14. Notes that, according to the Court's report, since 2014 the Agency has undergone two major re-organisations including the internal re-allocation of top and middle management positions; notes moreover that the re-allocation of key staff in the area of IT and administration was not successful, causing material risk of instability to the Agency and its operations; notes however that the Agency considers that no instability was suffered by the Agency due to organisational changes ***which aimed at increasing operational efficiencies and improving delivery of strategic objectives and which were supported by the Agency's Management***

attention to these issues, improve its human resources management and report back to the discharge authority;

**Board**; notes moreover that there is no system in place to analyse skills availability, identify gaps and to recruit and allocate appropriate staff; calls on the Agency to pay extra attention to these issues, improve its human resources management and report back to the discharge authority;

Or. en

## **Amendment 9**

**Bart Staes**

on behalf of the Verts/ALE Group

### **Motion for a resolution**

#### **Paragraph 16**

##### *Motion for a resolution*

16. Notes that, according to the Court's report, in 2014 the Commission, on behalf of more than 50 Union Institutions and bodies (including the Agency) signed a framework contract with one contractor for the acquisition of software, licences and the provision of related IT maintenance and consultancy; notes that the framework contractor acts as an intermediary between the Agency and suppliers that can address the Agency's needs; takes note that for these intermediary services, the framework contractor is entitled to a commission of two to nine percent of the suppliers' prices; observes that in 2016, total payments to the framework contractor amounted to EUR 8 900 000; regrets that the Agency did not systematically check prices and uplifts charged with the suppliers' quotes and invoices issued to the framework contractor; ***calls on the Agency to pay extra attention to such issues, to regularly check the prices and look at means of better economising on its operations;***

##### *Amendment*

16. Notes that, according to the Court's report, in 2014 the Commission, on behalf of more than 50 Union Institutions and bodies (including the Agency) signed a framework contract with one contractor for the acquisition of software, licences and the provision of related IT maintenance and consultancy; notes that the framework contractor acts as an intermediary between the Agency and suppliers that can address the Agency's needs; takes note that for these intermediary services, the framework contractor is entitled to a commission of two to nine percent of the suppliers' prices; observes that in 2016, total payments to the framework contractor amounted to EUR 8 900 000; regrets that the Agency did not systematically check prices and uplifts charged with the suppliers' quotes and invoices issued to the framework contractor; ***notes however that, following the Court's finding in October 2017, the Agency investigated the case which resulted in contractor's acknowledgment of their mistake and an expected recovery of approximately EUR 12 000; also notes that, since October 2017, specific internal guidance has been put in place by the Agency; that guidance includes systematic***

*checks of product category and related uplift for every quotation received from Comparex with value above EUR 60 000;*

Or. en

**Amendment 10**

**Dennis de Jong**

**Motion for a resolution**

**Paragraph 16 a (new)**

*Motion for a resolution*

*Amendment*

*16 a. Acknowledges from the Agency that pre-submission meetings contribute to the development of medicines; notes that in the light of the pre-submission meetings, the experts of the Committee for Medicinal Products for Human Use perform both the role of consultant as of evaluator of the marketing authorisation applications; calls upon the Agency to at least publish a list of pre-submission activities, once the marketing authorisation has been given;*

Or. en

**Amendment 11**

**Dennis de Jong**

**Motion for a resolution**

**Paragraph 16 b (new)**

*Motion for a resolution*

*Amendment*

*16 b. Acknowledges that approvals of marketing authorisation applications are based on three criteria: efficacy, quality and safety; notes that a fourth requirement should be added: Added Therapeutic Value (ATV), comparing a medicine with the best available drug, instead of comparing it to placebos;*

Or. en



#### **Amendment 12**

**Monica Macovei, Ryszard Czarnecki, Dennis de Jong, Richard Sulík, Petri Sarvamaa, Patricija Šulin, Tomáš Zdechovský**

#### **Motion for a resolution**

##### **Paragraph 19**

###### *Motion for a resolution*

19. Notes with satisfaction that the declarations of interests of all Management Board members are published on the Agency's website; notes that no breach of trust procedures were initiated for Management Board members in 2016;

###### *Amendment*

19. Notes with satisfaction that the **CVs** **and** declarations of interests of all Management Board members are published on the Agency's website; notes that no breach of trust procedures were initiated for Management Board members in 2016;

Or. en

#### **Amendment 13**

**Dennis de Jong**

#### **Motion for a resolution**

##### **Paragraph 20 a (new)**

###### *Motion for a resolution*

###### *Amendment*

**20 a. Asks the Agency for clarification concerning the hiring of and dependence on IT consultants for IT projects; notes that no methodology had been put in place prior to the start of the projects, affecting the supervision and monitoring by the management; is concerned about the limited supervision of the external consultants as a result of the contracts used and the fact that performance takes place off-site and in other Member States, resulting, therefore, in delays in the projects' implementation;**

Or. en

#### **Amendment 14**

**Monica Macovei, Dennis de Jong**

**Motion for a resolution**  
**Paragraph 20 a (new)**

*Motion for a resolution*

*Amendment*

**20 a. Notes that the relocation of the Agency could lead to staff leaving the Agency; calls therefore on the Agency to make sure that revolving door rules are strictly applied in each case;**

Or. en

**Amendment 15**  
**Monica Macovei**

**Motion for a resolution**  
**Paragraph 22**

*Motion for a resolution*

*Amendment*

22. Takes note that the Agency has adopted the Commission guidelines on internal whistleblowing in November 2014; welcomes the adoption by the Agency's Management Board of a policy to handle external sources' reports on matters within the scope of its responsibilities (i.e. external whistleblowing rules) in March 2017;

22. Takes note that the Agency has adopted the Commission guidelines on internal whistleblowing in November 2014; welcomes the adoption by the Agency's Management Board of a policy to handle external sources' reports on matters within the scope of its responsibilities (i.e. external whistleblowing rules) in March 2017; ***calls on the Internal Control Unit to perform random verifications in cooperation with heads of divisions to strengthen measures for detection of suspicious behaviors and deterrence; recommends that the Agency subjects its conflict of interest policies to an independent assessment;***

Or. en

**Amendment 16**  
**Benedek Jávor, Bart Staes**  
on behalf of the Verts/ALE Group

**Motion for a resolution**  
**Paragraph 22 a (new)**

**22 a.** *Expresses the need to establish an independent disclosure, advice and referral body with sufficient budgetary resources, in order to help whistleblowers use the right channels to disclose their information on possible irregularities affecting the financial interests of the Union, while protecting their confidentiality and offering needed support and advice;*

Or. en

**Amendment 17**  
**Monica Macovei**

**Motion for a resolution**  
**Paragraph 23**

*Motion for a resolution*

23. Acknowledges from the Agency that in 2016, it recorded no internal whistleblower ***cases*** and received 18 reports from an external source concerning alleged improprieties of a regulatory nature, potentially adversely affecting public health; notes that the Agency followed-up on each of these reports but did not identify any safety/efficacy concerns entailing the need to take specific regulatory action;

*Amendment*

23. Acknowledges from the Agency that in 2016, it recorded no internal whistleblower ***case*** and received 18 reports from an external source concerning alleged improprieties of a regulatory nature, potentially adversely affecting public health; notes that the Agency followed-up on each of these reports but did not identify any safety/efficacy concerns entailing the need to take specific regulatory action; ***acknowledges that internal procedures are not sufficient to identify concerns or irregularities; calls on the Agency to refer those cases to an independent authority;***

Or. en

**Amendment 18**  
**Petri Sarvamaa**

**Motion for a resolution**  
**Paragraph 24**

*Motion for a resolution*

24. Notes that in 2016 the Agency received 823 requests for access to documents which represent a 20 % increase compared to 2015; notes that the Agency replied to 678 requests and granted full access to 542 requests, 17 requests were granted only partial access and 44 requests were refused; notes that the reason given by the Agency for refusing 21 requests to access to documents was the protection of commercial interests; calls on the Agency to ensure that, when deciding on limiting the access to documents due to protection of commercial interests, it also considers the Union and its citizens' interest in health with *utmost* seriousness;

*Amendment*

24. Notes that in 2016 the Agency received 823 requests for access to documents which represent a 20 % increase compared to 2015; notes that the Agency replied to 678 requests and granted full access to 542 requests, 17 requests were granted only partial access and 44 requests were refused; notes that the reason given by the Agency for refusing 21 requests to access to documents was the protection of commercial interests; calls on the Agency to ensure that, when deciding on limiting the access to documents due to protection of commercial interests, it also considers the Union and its citizens' interest in health with seriousness, *while applying relevant rules and regulations*;

Or. en

**Amendment 19**  
**Petri Sarvamaa**

**Motion for a resolution**  
**Subheading 9**

*Motion for a resolution*

*Performance-based budgeting*

*Amendment*

*Main achievements*

Or. en

**Amendment 20**  
**Petri Sarvamaa**

**Motion for a resolution**  
**Paragraph 30**

*Motion for a resolution*

30. Notes in particular that the Agency will be facing an additional workload and budgetary needs throughout the 2018-2020 relocation and transition period as a consequence of the decision of the United

*Amendment*

30. Notes in particular that the Agency will be facing an additional workload and budgetary needs throughout the 2018-2020 relocation and transition period as a consequence of the decision of the United

Kingdom (UK) to withdraw from the Union; calls on the Commission to make available **additional** staff and budget resources during this period to ensure that the Agency can both continue to carry out its tasks effectively and launch all required activities in preparation of its relocation in 2019; proposes in addition that the Agency, limited by legislation and in line with the principle of sound financial management, be authorised to maintain a budgetary reserve generated from revenue fees to respond to unforeseen costs and unfavourable exchange rate fluctuations that may be incurred in 2018 and beyond;

Kingdom (UK) to withdraw from the Union; calls on the Commission to make available **adequate** staff and budget resources during this period to ensure that the Agency can both continue to carry out its tasks effectively and launch all required activities in preparation of its relocation in 2019; proposes in addition that the Agency, limited by legislation and in line with the principle of sound financial management, be authorised to maintain a budgetary reserve generated from revenue fees to respond to unforeseen costs and unfavourable exchange rate fluctuations that may be incurred in 2018 and beyond;

Or. en

**Amendment 21**  
**Monica Macovei**

**Motion for a resolution**  
**Paragraph 31 a (new)**

*Motion for a resolution*

*Amendment*

**31 a. Welcomes the Parliament's mission to Amsterdam, at the temporary and future headquarters of the Agency, to gather up-to-date information on the progress of the double transfer and on the development of the real estate project and underlines the role of the Parliament in the decision-making process regarding the new headquarters;**

Or. en

**Amendment 22**  
**Petri Sarvamaa**

**Motion for a resolution**  
**Paragraph 33**

*Motion for a resolution*

*Amendment*

33. Notes that the Court issued an  
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33. Notes that the Court issued an  
13/15 PE618.255v01-00

emphasis of matter paragraph for the two London-based agencies, concerning the UK's decision to withdraw from the Union; notes that in view of the decisions on the future location of the Agency, it has disclosed in its financial statements an estimated EUR 448 000 000 rent for the remaining rental period between 2017 and 2039 as a contingent liability, as the rental contract does not include any exit clause; notes moreover that contingent liabilities in relation to other costs associated with a removal such as, for example the relocation of staff together with their families, actions to mitigate a potential loss of internal and UK-based external expertise, and consequent risk to business continuity, are yet to be determined; calls on the Agency to report to the discharge authority on an updated estimate of relocation costs, which includes liability of the current premises;

emphasis of matter paragraph for the two London-based agencies, concerning the UK's decision to withdraw from the Union; notes that in view of the decisions on the future location of the Agency, it has disclosed in its financial statements an estimated EUR 448 000 000 rent for the remaining rental period between 2017 and 2039 as a contingent liability, as the rental contract does not include any exit clause; ***urges the Commission to take responsibility of these absurdly high liabilities and, together with the Agency, negotiate an acceptable deal with the lessor***; notes moreover that contingent liabilities in relation to other costs associated with a removal such as, for example the relocation of staff together with their families, actions to mitigate a potential loss of internal and UK-based external expertise, and consequent risk to business continuity, are yet to be determined; calls on the Agency to report to the discharge authority on an updated estimate of relocation costs, which includes liability of the current premises;

Or. en

### **Amendment 23** **Dennis de Jong**

#### **Motion for a resolution** **Paragraph 34**

##### *Motion for a resolution*

34. Points out from the Court's report that the Agency's 2016 budget was financed 95 % by fees from pharmaceutical companies and 5 % from Union funds; ***takes note that a future decrease of the Agency's revenue resulting from the UK's decision to leave the Union is possible;***

##### *Amendment*

34. Points out from the Court's report that the Agency's 2016 budget was financed 95 % by fees from pharmaceutical companies and 5 % from Union funds; ***stresses that the funding from pharmaceutical companies has increased in 2016, comparing to 2015 and is concerned about the influence of the industry on the Agency as of this dependence;***

