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DRAFT REPORT

on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2016
(2017/2154(DEC))

Committee on Budgetary Control

Rapporteur: Bart Staes

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1. PROPOSAL FOR A EUROPEAN PARLIAMENT DECISION

on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2016
(2017/2154(DEC))

The European Parliament,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2016,

– having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2016, together with the Agency's reply[1],

– having regard to the statement of assurance[2] as to the reliability of the accounts and the legality and regularity of the underlying transactions provided by the Court of Auditors for the financial year 2016, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of ... February 2018 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2016 (00000/2018 – C8-0000/2018),

– having regard to Article 319 of the Treaty on the Functioning of the European Union,

– having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002[3], and in particular Article 208 thereof,

– having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[4], and in particular Article 68 thereof,

– having regard to Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council[5], and in particular Article 108 thereof,

– having regard to Rule 94 of and Annex IV to its Rules of Procedure,

– having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on the Environment, Public Health and Food Safety (A8-0000/2018),

[1] OJ C 417, 6.12.2017, p. 142.
[2] OJ C 417, 6.12.2017, p. 142.
[3] OJ L 298, 26.10.2012, p. 1.
[4] OJ L 136, 30.4.2004, p. 1.
[5] OJ L 328, 7.12.2013, p. 42.

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;

2. Sets out its observations in the resolution below;

3. Instructs its President to forward this decision, and the resolution forming an integral part of it, to the Executive Director of the European Medicines Agency, the Council, the Commission and the Court of Auditors, and to arrange for their publication in the *Official Journal of the European Union* (L series).

2. PROPOSAL FOR A EUROPEAN PARLIAMENT DECISION

on the closure of the accounts of the European Medicines Agency for the financial year 2016
(2017/2154(DEC))

The European Parliament,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2016,

– having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2016, together with the Agency's reply[1],

– having regard to the statement of assurance[2] as to the reliability of the accounts and the legality and regularity of the underlying transactions provided by the Court of Auditors for the financial year 2016, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of ... February 2018 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2016 (00000/2018 – C8-0000/2018),

– having regard to Article 319 of the Treaty on the Functioning of the European Union,

– having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002[3], and in particular Article 208 thereof,

– having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[4], and in particular Article 68 thereof,

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– having regard to Rule 94 of and Annex IV to its Rules of Procedure,

– having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on the Environment, Public Health and Food Safety (A8-0000/2018),

[1] OJ C 417, 6.12.2017, p. 142.
[2] OJ C 417, .6.12.2017, p. 142.
[3] OJ L 298, 26.10.2012, p. 1.
[4] OJ L 136, 30.4.2004, p. 1.
[5] OJ L 328, 7.12.2013, p. 42.

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;

2. Instructs its President to forward this decision to the Executive Director of the European Medicines Agency, the Council, the Commission and the Court of Auditors, and to arrange for its publication in the *Official Journal of the European Union* (L series).

3. MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2016
(2017/2154(DEC))

The European Parliament,

– having regard to its decision on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2016,

– having regard to Rule 94 of and Annex IV to its Rules of Procedure,

– having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on the Environment, Public Health and Food Safety (A8-0000/2018),

A. whereas in the context of the discharge procedure, the discharge authority wishes to stress the particular importance of further strengthening of the democratic legitimacy of the Union institutions by improving transparency and accountability and implementing the concept of performance-based budgeting and good governance of human resources;

B. whereas, according to its statement of revenue and expenditure[1], the final budget of the European Medicines Agency ("the Agency") for the financial year 2016 was EUR 308 422 000, representing an increase of 0,1 % compared to 2015;

C. whereas the Agency is a fee-funded agency, with 89,34% of its 2016 revenue stemming from fees paid by the pharmaceutical industry, for services provided, 5,49% stemming from the Union budget to fund various public health and harmonisation activities, and 5,01% stemming from external assigned revenue;

D. whereas the Court of Auditors ("the Court") in its report on the annual accounts of the European Medicines Agency for the financial year 2016 ("the Court's report"), has stated that it has obtained reasonable assurances that the Agency's annual accounts are reliable and that the underlying transactions are legal and regular;

Follow-up of 2014 discharge

1. Notes with concern that some of the Court's comments from the 2014 discharge are still not marked as "completed", in particular the evaluation of the weaknesses in management control, the distribution of appropriate pharmacovigilance information to the Member States and to the general public; calls on the Agency to complete the corrective actions as soon as possible in 2018 and to report to the discharge authority on their implementation;

Comments on the reliability of the accounts

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

[1] OJ C 443, 29.11.2016, p.4

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;

Comments on the legality and regularity of transactions

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;

Budget and financial management

4. Notes that budget monitoring efforts during the financial year 2016 resulted in a budget implementation rate of 96,30 %, representing an increase of 2,25 % compared with the previous year; notes furthermore that the payment appropriations execution rate was at 85,51 %, representing a decrease of 1,58 %;

Commitments and carry-overs

5. Notes that no specific comments were issued by the Court as regards the Agency's carry-overs; notes in addition that the Agency fully complied with relevant financial rules and key performance indicators for the amounts carried over, resulting in carry-overs for Title I at 0,86 %, for Title II at 7,93 % and for Title III at 25,86 %;

6. Points out that carry-overs are often partly or fully justified by the multiannual nature of the agencies' operational programmes, do not necessarily indicate weaknesses in budget planning and implementation and are not always at odds with the budgetary principle of annuality, in particular if they are planned in advance and communicated to the Court;

Transfers

7. Notes with satisfaction that, according to the Agency's annual activity report, the level and nature of transfers in 2016 remained within the limits of the financial rules; acknowledges from the Agency that during 2016 it made twelve transfers totalling EUR 9 268 000 or 3% of final appropriations; notes that the transferred expenditure appropriations were primarily needed to cover increased expenditure on business IT development; increased appropriations for rapporteurs and pharmacovigilance services and reduction of appropriations, where expenditure is mainly paid in pound sterling;

Procurement and staff policy

8. Observes from the Agency's establishment plan that 587 posts (out of 602 posts authorised under the Union budget) were occupied on 31 December 2016, as it was in

2015; notes that in addition the Agency was employing (in FTEs) 36 seconded national experts, 143 contract staff, 59 interim staff and 148 consultants;

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;

10. Notes that on average the Agency's staff was on sick leave 7,9 days in 2016; observes with satisfaction that the Agency put in place a health & safety group for consultation with staff, provides its staff with healthy food options in the Agency canteen and made an annual contribution of £ 31 108,33 to the Sports and Leisure Club that arranges activities such as a summer party and a Christmas party and also has nine sport and leisure activity clubs within the areas of art, books, cinema, theatre, basketball, football, mountain sports, Nordic walking and volleyball;

11. Notes with satisfaction that the Agency has a policy in place for protecting the dignity of the person and preventing any form of psychological or sexual harassment; notes that the Agency also has listening points (confidential counsellors) in place for staff to bring their concerns within the informal procedure; notes that there were no harassment cases in 2016;

12. Notes that the Agency does not have any official vehicles;

13. Notes that the result of the staff engagement survey carried out in 2015 represented a further improvement compared to 2013; observes however that remaining issues identified include collaboration across divisions, objectivity in decision-making processes and trust in senior management; notes that a focus group proposed eight improvement actions for the three areas of improvement; acknowledges that six of the proposals were endorsed by the Executive Board, out of which three are already in the implementation phase (internal mobility database; fact sheets for communication of decisions; regular team meetings), and three more are planned to follow (360 degree feedback process; personnel communication plan; better support for line managers); calls on the Agency to report to the discharge authority on the implementation of these actions;

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

15. Notes that, according to the Court's report, the Agency is critically dependent on

external expertise since the start of the projects, yet there is no policy in place to govern the use of consultants; regrets that quality issues identified upon receipt of deliverables required rectification for which additional cost was charged to the Agency; calls on the Agency to better use its own resources and tries to limit the dependency on external expertise, to prepare and set up a proper policy to govern the use of external consultants and to report to the discharge authority on its implementation;

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;

Prevention and management of conflicts of interests, transparency and democracy

17. Notes that the revised policy on the handling of competing interests of the Management Board members came into effect on 1 May 2016 and was further revised in October 2016; acknowledges from the Agency that the implementation of the revised policy now includes an ex ante evaluation which is performed to compare the details contained in each new declaration, with those of the previous declaration, and with the CV of each board member provided;

18. Welcomes the fact that the names of members having declared competing interests, which could affect their impartiality with regard to specific items on the agenda, are noted in the minutes and that it may imply some restriction on their involvement at the meeting;

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;

20. Observes that the Agency's Code of Conduct extends the requirements for impartiality and the submission of annual declarations of interests to all members of staff of the Agency, including temporary agents, contract agents, seconded national experts, interims, visiting experts and trainees; notes that the decision concerning the handling of declared interests of members of staff of the Agency and candidates before recruitment was revised as a result of the review of both the policy on the handling of declarations of interests of scientific committee members and experts, and the policy on competing interests of the Management Board members and became effective as of 1 January 2017;

21. Notes that the Agency's anti-fraud office delivered on the targeted actions, outlined in the Agency anti-fraud strategy for 2016; all staff were requested to attend the Agency's

e-learning course, covering anti-fraud related matters, and entirely prepared in-house by the anti-fraud office;

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;

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;

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;

Performance-based budgeting

25. Welcomes the main achievements identified by the Agency in 2016, namely:

– the Agency fulfilled its legal obligations of supporting innovation, authorisation and supervision of medicinal products thus promoting and protecting public health;

– the Agency started publishing clinical data underpinning marketing authorisation applications for new medicines as the first regulator in the world;

– the Agency launched PRIority MEdicines (PRIME), a new scheme to reinforce regulatory support to optimise the development of medicines that address patients’ unmet needs;

– together with the European Food Safety Authority, the Agency reviewed the measures to reduce the use of antimicrobials in food-producing animals and delivered a joint scientific opinion;

Internal controls

26. Takes note that the Agency has developed a sustainable process to identify, assess, and manage risks across the organisation, to ensure attainment of key organisational objectives; notes that none of the identified risks were considered critical and none had materialised during 2016;

27. Notes that the effectiveness of the Agency's Internal Control Standards was assessed via

an internal questionnaire addressed to the Agency's management; acknowledges that the assessment concluded that the system in place is generally compliant with the standards, thus providing the Agency with reasonable assurance on the reliability of the internal control environment, even though three areas for improvement were highlighted; namely — staff allocation and mobility, objectives and performance indicators and operational structure; notes that measures have been taken to further improve the efficiency and application of the standards above, and an action plan to rectify the above areas has been drafted and it will be implemented in 2017; calls on the Agency to report to the discharge authority on the implementation of the action plan;

Internal audit

28. Notes that 10 recommendations marked as "Very Important" and stemming from audits carried out by the Agency's Internal Audit Capability up to 31 December 2015, were still open at the end of 2016; notes that no critical recommendations remain open; calls on the Agency to report to the discharge authority on the measures taken to complete the open recommendations marked as "Very Important";

29. Notes with satisfaction that no recommendations marked as "Critical" or "Very Important" from the Commission's Internal Audit Service were open as of 31 December 2016;

Other Comments

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;

31. Stresses the need for the accelerated building approval procedure set out in Article 88 of the Agency's framework financial regulation so as to avoid any delays in the start of the construction of the new Agency's premises in Amsterdam;

32. In the context of the Agency's impending relocation to Amsterdam and the need to secure the highest possible retention of staff, supports a broad interpretation of point (a) of Article 12(2) of the Conditions of Employment of Other Servants of the Union, thus enabling the Executive Director to retain the highest possible number of the Agency's staff members of UK nationality until 29 March 2019 and beyond;

33. Notes that the Court issued an *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;

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;

35. Notes that the assessment of risks related to 'Brexit' has been performed separately by the Operations and Relocation Preparedness Task Force (ORP taskforce) of the Agency, set up to ensure the Agency preparedness for various development scenarios following Brexit; notes that in 2016, the taskforce was focused on the assessment of the impact on the Agency, including managing preparations related to support for staff and delegates, financial matters, security issues and infrastructure, in the event of relocation to another country; calls on the Agency to report to the discharge authority on the measures taken to face this challenge;

36. Acknowledges from the follow-up report that the ORP Task Force has officially stated that all costs for the early departure from London and relocation of the Agency to the new host Member State will have to be borne by the UK Government; acknowledges moreover that, in the meantime, as tenant, the Agency is analysing all possible options with the assistance of UK-based legal and real estate advisors, whilst keeping an eye on the negotiations between the Union and the UK Government;

37. Notes that, according to the Court's report, Regulation (EC) No 726/2004 requires an external evaluation of the Agency and its operations by the Commission every ten years; observes that the last evaluation report was issued in 2010; agrees with the Court's comment that such a long time span does not ensure timely performance feedback to stakeholders; acknowledges from the Agency that the Commission is currently preparing the next evaluation to be conducted in the period 2017-2018;

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38. Refers, for other observations of a cross-cutting nature accompanying its decision on discharge, to its resolution of [xx April 2018[1]] [on the performance, financial management and control of the agencies].

[1] Texts adopted of that date, P8_TA-PROV(2018)0000.