European Parliament
2014-2019

TEXTS ADOPTED

P8_TA(2017)0172

Discharge 2015: European Medicines Agency (EMA)

1. European Parliament decision of 27 April 2017 on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2015 (2016/2169(DEC))

The European Parliament,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2015,

– having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2015, 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 2015, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of 21 February 2017 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2015 (05873/2017 – C8-0055/2017),

– 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

1 OJ C 449, 1.12.2016, p. 123.
2 OJ C 449, 1.12.2016, p. 123.
3 OJ L 298, 26.10.2012, p. 1.
4 OJ L 136, 30.4.2004, p. 1.

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[1], 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 (A8-0084/2017),

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 2015;

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).

[1] OJ L 328, 7.12.2013, p. 42.

2. European Parliament decision of 27 April 2017 on the closure of the accounts of the European Medicines Agency for the financial year 2015 (2016/2169(DEC))

The European Parliament,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2015,

– having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2015, 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 2015, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of 21 February 2017 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2015 (05873/2017 – C8-0055/2017),

– 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 (A8-0084/2017),

1. Approves the closure of the accounts of the European Medicines Agency for the financial year 2015;

2. Instructs its President to forward this decision to the Executive Director of the European

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1 OJ C 449, 1.12.2016, p. 123.
2 OJ C 449, 1.12.2016, p. 123.
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.

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. European Parliament resolution of 27 April 2017 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 2015 (2016/2169(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 2015,

– 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 (A8-0084/2017),

A. whereas, according to its financial statements, the final budget of the European Medicines Agency ("the Agency") for the financial year 2015 was EUR 308 097 000 representing an increase of 9,07 % compared to 2014; whereas the increase was mainly due to a budgetary amendment that accounts for an increase in revenue from cash received for services rendered (EUR 5 000 000) and an adjustment in assigned revenue (EUR 980 000); whereas 11,1 % of the Office's budget derives from the Union budget,

B. whereas the Court of Auditors ("the Court") in its report on the annual accounts of the European Medicines Agency for the financial year 2015 ("the Court's report"), has stated that it has obtained reasonable assurances that the Agency's annual accounts for the financial year 2015 are reliable and that the underlying transactions are legal and regular,

Follow-up of 2014 discharge

1. Acknowledges from the Agency that:

- although there had been delays in the collection of fees as noted by the discharge authority, these had no impact on the Agency's and Member States' ability to perform their public health tasks, including pharmacovigilance activities; notes that all safety monitoring and regulatory activities have been performed as required by the pharmacovigilance legislation of the Union; acknowledges furthermore the fact that financial transactions concerning pharmacovigilance fees are handled separately from the Agency's core responsibility, as well as the fact that, according to the Commission report on "Pharmacovigilance related activities of Member States and the European Medicines Agency concerning medicinal products for human use (2012 – 2014)", the Agency managed the pharmacovigilance-related activities successfully;

- all its planned procurements are included in the Agency's work programme which is adopted by its management board, and are in line with the requirements of the financial regulation; acknowledges the fact that all specific contracts stemming from the framework contract on consultancy services were triggered by the legislative responsibilities of the agency and its business needs, and are supported by documents specifying activities, objectives and requirements;

- it is committed to further strengthening its guidelines for harmonised implementation of conflicts of interest as a selection criteria in its procurement procedures;

Budget and financial management

2. Notes that budget monitoring efforts during the financial year 2015 resulted in a budget implementation rate of 94,05 %, representing a decrease of 0,27 % compared with the previous year; notes furthermore that the payment appropriations execution rate was at 87,09 %, representing an increase of 4,79 %;

3. Recalls that, as stipulated in its financial regulation, budget revenue of the Agency is based on cash received from the Union for contributions, fees for marketing authorisation applications for pharmaceutical products and for post-authorisation activities as well as for various administrative activities;

Commitments and carryovers

4. Notes with satisfaction that the rate of committed appropriations carried forward to 2016 declined to 14,78 %, from 17,70 % in 2014; acknowledges the fact that the non-automatic carry-forward to 2016 was made in accordance with its financial regulation, and covered various IT developments, business consultancy and scientific studies; points out that these carry-forwards do not indicate weaknesses in budget planning and implementation, nor are they at odds with the budgetary principle of annuality, as the expenditure could not be implemented in 2015 due to reasons outside the control of the Agency;

Transfers

5. Notes with satisfaction that, according to the annual activity report, the level and nature of transfers in 2015 remained within the limits of the financial rules; acknowledges from the Agency that during 2015 it made nine transfers totalling EUR 22 026 000 or 7,15 % of final appropriations, representing a decrease of 4,7 %; notes that the transferred expenditure appropriations were primarily needed to cover expenditure on business IT development and adjustments to budget items for administrative expenditure;

Procurement and recruitment procedures

6. Notes that the result of the staff engagement survey carried out in 2015 represented a further improvement compared to 2013; observes however that identified remaining issues include collaboration across divisions, objectivity in decision-making processes and trust in senior management; acknowledges from the Agency that it created an action plan to address the remaining issues and adopted it in 2016; calls on the Agency to report to the discharge authority on the implementation results of the action plan;

7. Recalls that the workload of the Agency is constantly growing and reflected in the budgetary increases in income from fees charged to applicants; notes with concern that the imposed staff cuts in recent years included staff working on tasks financed by applicants' fees without regard to the workload involved; strongly supports, therefore, the introduction of flexibility and coherence in adjusting the number of establishment plan posts for staff working on tasks financed by applicants' fees, in line with increasing demand;

8. Recalls that following the judgment of the Civil Service Tribunal, which was announced on 13 November 2014, annulling the Commission's decision to adopt a shortlist of

potential candidates for the position of Executive Director of the Agency and, as a consequence, the Board's appointment of the Executive Director in November 2011, the post was re-advertised and the Executive Director reappointed and that, despite that difficult situation, the Agency delivered its work programme;

Prevention and management of conflicts of interests and transparency

9. Acknowledges from the Agency that its revised policy on the handling of declarations of interests of scientific committees' members and experts entered into force in 2015; welcomes the fact that the declarations of interests of experts involved in the Agency's activities after the policy implementation date were evaluated against the revised policy; notes that the Agency performed systematic ex ante controls on the declarations of interests of new experts; notes moreover the conclusion of the annual ex post control on the handling of declarations of interests of committee members and experts participating in meetings; observes that the Agency updated the policy in October 2016 to further clarify the restrictions applied when an expert takes up a job in industry and to align the restriction applied in the case of close family members of committee, and working party members with interests in the industry, with those already applied to management board members; calls on the Agency to provide the discharge authority with a summary of the impact assessment of the revised policy;

10. Observes that the revised policy on handling of declared interests of members of staff of the Agency and candidates before recruitment was finalised in October 2016; notes that this revision ensured alignment, where relevant, with the revised policies in place for management board members and scientific committee members and experts;

11. Notes that the revised policy on handling competing interests for the Agency's management board members was adopted by its management board in December 2015; also notes that the new policy entered into force in May 2016;

12. Notes that in June 2016, the Agency's management board adopted an overarching Framework for Stakeholder Relation Management which outlines the principles for the management of its key stakeholder interactions and highlights transparency as an essential principle when managing such relations; observes that in 2015 the management board adopted a formalised framework for interactions with its industry stakeholders and published an annual report on its engagement with them; notes also that eligibility criteria for industry stakeholders were finalised in June 2016 for implementation in 2017 and that a list of industry stakeholder organisations that are eligible according to these criteria was published on the Agency's website in January 2017;

13. Observes that the "Breach of trust procedure for scientific committees' members/experts" was updated in April 2015; observes that this procedure sets out how the Agency deals with incorrect or incomplete declarations of interests by experts and committee members; acknowledges the fact that the Agency immediately restricts scientific committee or working party members from any participation in the evaluation of medicines when they intend to take up employment in a pharmaceutical company;

14. Notes that the Agency established an anti-fraud office as part of its anti-fraud strategy; takes note that the Agency conducted an internal survey of senior management which benchmarked anti-fraud awareness, and developed and launched a mandatory anti-fraud

e-learning course for all staff; notes furthermore that standard procurement contracts were amended to include anti-fraud clauses;

15. Observes that the Agency adopted the Commission guidelines on internal whistleblowing in November 2014; notes also that the Agency is currently working on a policy to handle external sources' reports on matters within the scope of its responsibilities (i.e. external whistleblowing rules), and that approval of this new policy is planned to occur by the end of 2017; welcomes this policy which should strengthen even further the Agency's efforts to disseminate a culture of integrity and compliance in the preparation and submission of regulatory documents;

16. Notes with satisfaction that new rules to reinforce the current cooling-off periods for the Agency's experts and staff have been implemented since 31 December 2016;

17. Notes with satisfaction that in 2015, the Agency adopted a new five-year framework strategy for corporate communications, which addressed findings from a stakeholder survey carried out that year; notes that this strategy lays out how the Agency intends to make its communications more effective in order to support the Agency in meeting its mission, goals and corporate priorities in promoting public health in the Union;

18. Reminds the Agency that Directive 2003/63/EC states that medicines can only be considered for Union marketing authorisation if they have been tested in accordance with ethical guidelines, and reminds the Agency of its commitment to perform extra checks on clinical trials carried out outside the European Union before granting a drug market authorisation[1]; therefore, due to the special vulnerabilities of those tests, asks the Agency to report to the discharge authority every year on actions taken to ensure drugs for the Union market were tested ethically in lower and middle income countries, in accordance with the law;

19. Encourages the Agency to further raise awareness of its conflict-of-interest policy among its staff, alongside ongoing awareness-raising activities and the inclusion of integrity and transparency as obligatory items to be discussed during recruitment procedures and performance reviews;

Performance

20. Notes with satisfaction that the Agency achieved its targets for the majority of the monitored qualitative and quantitative performance indicators presented in its annual activity report; observes that this extensive set includes the performance indicators such as the percentage of filled posts on the Agency establishment plan, the percentage of payments made within the limits of the financial regulation, or the satisfaction level of partners and/or stakeholders with the Agency's communications;

Internal controls

21. Observes that in 2014, the Agency carried out an analysis of potential risks that could impact achievement of the Agency's objectives; notes that none of the identified risks

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1 Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted outside of the EU/EEA and submitted in marketing authorisation applications to the EU Regulatory Authorities (European Medicines Agency document EMA/121340/2011).

were considered critical and none had materialised during 2015;

22. Notes that the effectiveness of the Agency's internal control standards (ICS) was assessed via an internal questionnaire addressed to the Agency's management; acknowledges the fact that the assessment concluded that the ICS are being implemented effectively; notes furthermore that the Agency intends to take measures in order to further improve the efficiency and application of the ICS concerning objectives and performance indicators, operational structure, document management, and information and communication;

Internal audit

23. Notes that 11 recommendations marked as "Very Important" and stemming from audits carried out by the Agency's Internal Audit Capability (IAC) were open at the end of 2015; acknowledges the fact that all of these recommendations were within the timeline agreed with the IAC;

24. Notes with satisfaction that no recommendation marked as "Critical" or "Very Important" from the Commission's Internal Audit Service (IAS) was open as of 31 December 2015; acknowledges the fact that in 2015 the IAS carried out an audit in the area of paediatric regulation procedures and that it did not identify any critical or very important issues;

25. Observes that in 2015, the Agency's IAC carried out audits in several areas, with no critical recommendations open at year-end; notes that, in the areas of security of product-related information, building blocks of assurance and video surveillance, the audits identified space for further improvements; acknowledges the fact that the Agency prepared action plans to address the identified issues; calls on the Agency to provide the discharge authority with the results of implemented actions;

Other Comments

26. Notes that 2015 marked the 20th anniversary of the Agency and the 50th anniversary of pharmaceutical legislation in the Union;

27. Notes that in 2015 the Agency recommended 93 medicines for marketing authorisation and that those include 39 new active substances; stresses that those substances have previously never been authorised in a medicine in the Union and are not related to the chemical structure of any other authorised substance;

28. Underlines that the Agency should continue promoting dialogue with stakeholders and citizens and incorporate it as part of the priorities and activities to be implemented;

29. Reiterates the important role of the Agency in protecting and promoting public and animal health by assessing and supervising medicines for human or veterinary use;

30. Acknowledges the fact that the Agency launched a pilot project in March 2014 on the safe use of adaptive pathways; notes that that pilot project aims to identify the appropriate tools, within the current regulatory framework, to bring to market medicines that address unmet medical needs for a defined patient population, and to ensure that marketing authorisation will only be granted if there is a positive balance of benefits and risks, without compromising patient safety or changing the standards of regulatory

approval;

31. Notes that on 23 June 2016, the citizens of the United Kingdom (UK) voted to leave the Union; points out that Article 50 of the Treaty on European Union provides that a Member State which decides to withdraw from the Union shall notify the European Council of its intention and the Union shall negotiate and conclude an agreement with that State, setting out the arrangements for its withdrawal; acknowledges from the Court's report that the accounts and related notes of the Agency, which is located in London (UK), were prepared using the information available at the date of signing of these accounts when the results of the referendum were not yet known, and that the formal notification of the triggering of Article 50 had not been presented;

32. Observes that following the outcome of the UK referendum on 23 June 2016, the Agency established a dedicated task force to focus on relocation preparedness, operational and financial preparedness, HR-related matters and communication (internal and external) aspects; observes that the work currently ongoing is focussed on the impact of a loss of EMA staff in the event of relocation and loss of external expertise due to the potential unavailability of UK expertise in the scientific committees and other EMA fora; notes that an impact assessment including remedial solutions should be available by the end of the first quarter of 2017;

33. Welcomes the information provided by the Agency to the discharge authority on its current contractual commitments and liabilities linked to its physical presence in the UK; notes with concern that the Agency's rental contract until 2039 does not include an early termination clause to release the Agency from the liabilities of rent and associated costs, and that the payable rent for the remaining period from 2017 to 2039 is estimated at EUR 347,6 million; asks the Agency to report to the discharge authority on any developments on this matter;

34. Acknowledges the fact that the absence of a break clause was noted in the opinion of the Committee on Budgets of 24 May 2011 and that the rental agreement was signed in 2011 when a potential exit of the UK from the Union was not foreseeable; however, the costs associated with the relocation would reasonably be expected to be considered in the negotiations on the withdrawal agreement between the Union and the UK Government; asks the Agency to report to the discharge authority on any developments on this matter;

35. Stresses the risk of budgetary volatility faced by the Agency as a consequence of the outcome of the UK referendum on Union membership; proposes, in the spirit of sound financial management, that the Agency be authorised to maintain a budgetary reserve to respond to unforeseen costs that may need to be incurred in 2017 and unfavourable exchange rate fluctuation , or beyond, as a consequence of that decision, to ensure that the Agency can continue to carry out its tasks effectively; asks also in this respect the Agency to produce a comprehensive business continuity plan which deals with the double and connected risks of budgetary and business volatility;

36. Notes that the Agency launched a pilot project on "adaptive pathways" in March 2014 aiming to accelerate market authorisations for specific medicines using the so-called post-marketing authorisation; is concerned that the pilot project raises numerous public health concerns and undermines the core mission of the Agency, namely to ensure safety of medicines; asks the Agency to report to the discharge authority on the project

and the measures it has taken to ensure that this acceleration of the procedure does not undermine its core mission;

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37. Refers, for other observations of a cross-cutting nature accompanying its decision on discharge, to its resolution of 27 April 2017[1] on the performance, financial management and control of the agencies.

[1] Texts adopted, P8_TA(2017)0155.