

RESOLUTION (EU) 2019/1486 OF THE EUROPEAN PARLIAMENT**of 26 March 2019****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 2017**

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 2017,
 - 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 (A8-0135/2019),
- A. whereas, according to its statement of revenue and expenditure ⁽¹⁾, the final budget of the European Medicines Agency ('the Agency') for the financial year 2017 was EUR 331 266 000, representing an increase of 7,41 % compared to 2016; whereas the Agency is a fee-funded agency, with 86 % of its 2017 revenue stemming from fees paid by the pharmaceutical industry for services provided, and 12 % stemming from the Union budget;
- B. whereas the Court of Auditors ('the Court') in its report on the annual accounts of the Agency for the financial year 2017 ('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;

Budget and financial management

1. Notes that budget monitoring efforts during the financial year 2017 resulted in a budget implementation rate of 92,92 %, representing a decrease of 3,38 % compared to 2016; notes furthermore that the payment appropriations execution rate was 76,62 %, representing a decrease of 5,73 % compared to 2016;

Cancellation of carryovers

2. Regrets that the cancellations of carry-overs from 2016 to 2017 amounted to EUR 4 350 908, representing 10,11 % of the total amount carried-over, showing a notable increase of 5,65 % in comparison to 2016; calls on the Agency to report to the discharge authority on the measures taken to ensure complete use of the appropriations carried-over, in order to avoid substantial resources being de-committed;

Performance

3. Acknowledges that the Agency uses several key performance indicators, including a combination of operational, management/governance and communication/stakeholder indicators to measure its workload volumes, its work programme implementation and its stakeholders satisfaction amongst others, in order to assess the added value provided by its activities, and that it furthermore uses budget planning and monitoring methodology to enhance its budget management;
4. Acknowledges that the Agency implemented in November 2017 a new and improved version of the EudraVigilance system, an information system used to report suspected side effects of medicines;
5. 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;
6. Stresses that a number of the Agency's activities were delayed or postponed due to the United Kingdom's decision to withdraw from the European Union or external circumstances;
7. Highlights that in 2017, the Agency recommended 110 new medicines for marketing authorisation (92 for human use and 18 for veterinary use), and that those included 42 new active substances (35 for human use and 7 for veterinary use);

⁽¹⁾ OJ C 420, 7.12.2017, p. 3.

8. Welcomes the fact that in 2017 the Agency implemented a communication plan strengthening collaboration with national competent authorities, patient-and-consumer, and healthcare-professional organisations;
9. Notes with satisfaction that the Agency cooperates with other Agencies on joint scientific outputs and exchanges support or scientific data; acknowledges furthermore that the Agency has formal working arrangements with its five main Agency partners;
10. Notes that the Agency's management board adopted the multiannual work plan 2018-2020, which supports the implementation of the joint strategy for the European medicines regulatory network and furthermore outlines key initiatives and activities for the coming years;

Staff policy

11. Notes that, on 31 December 2017, the establishment plan was 97,82 % executed, with 583 temporary agents appointed out of 596 temporary agents authorised under the Union budget (compared with 602 authorised posts in 2016); notes that in addition 147 contract agents and 36 seconded national Experts worked for the Agency in 2017; notes that the staff expenses increased by 10 million euros; asks the Agency to report comprehensively on this expenditure; urges the Agency to not replace permanent staff by more expensive contract agents;
12. Notes that the Agency has adopted the Commission's model decision on the policy on protecting the dignity of the person and preventing harassment; acknowledges that the Agency put in place a system of confidential counsellors following an inter-agency call for expression and appointed a Harassment Prevention Coordinator;
13. Notes with concern that, according to the Agency and to the Court's report, while significant new tasks were assigned to the Agency, the Agency's staff establishment plan was not increased in 2017, leading to a critical dependence on external expertise in affected areas; welcomes that the management board of the Agency was verbally informed by DG SANTE representative that the Agency's request to hire up to 40 time-limited contract agents in 2019 has been accepted; welcomes the measures already taken by the Agency to mitigate the risks involved and calls on the Agency to report to the discharge authority on further decisions taken in order to improve the situation;
14. Welcomes the suggestion of the Court to publish vacancy notices also on the website of the European Personnel Selection Office in order to increase publicity; understands the Agency's concerns regarding translation costs;

Procurement

15. Notes that, according to the Court's report, by the end of 2017 the Agency had not yet introduced all of the tools launched by the Commission aimed at introducing a single solution for the electronic exchange of information with third parties that participate in public procurement procedures (e-procurement); notes that, according to the Agency's reply, it signed a Memorandum of Understanding with the Commission for access to and the use of e-submission; calls on the Agency to introduce all the necessary tools and report to the discharge authority on the progress made in that field;

Prevention and management of conflicts of interests and transparency

16. Stresses that the Agency's clients - the pharmaceutical industry - pay for the procedure, not for the outcome of the Agency's assessments; understands that according to the Agency it considers its recommendations to be made independently and that they, therefore, do not create conflicts of interest, in respect of which any potential risks are however duly considered, prevented and mitigated;
17. Welcomes the fact that the Agency also requests all IT consultants to sign individual declarations of interest and confidentiality undertaking at the beginning of their assignment;
18. Acknowledges the Agency's existing measures and ongoing efforts to secure transparency, prevention, management of conflicts of interest, and whistle-blower protection; notes with concern that in 2017 the Agency received 25 reports on cases of whistleblowing from an external source, 15 cases were closed in 2017 and 10 cases are still ongoing; calls on the Agency to report to the discharge authority on any developments in that regard;

19. Highlights that no breach of trust procedure was initiated for management board members, scientific committee members or experts, and that no cases of conflicts of interests were noted in relation to staff members in 2017;
20. Notes that the Agency meets with external stakeholders and has rules in place to govern its interactions with stakeholders and furthermore that it publishes the minutes of meetings with 'interest representatives' on its website; notes with satisfaction that the Agency developed a framework for stakeholder relation management in consultation with the Commission, which encompassed transparency measures;
21. Notes that, according to the Court's report, there is a need to strengthen the accounting officer's independence by making him directly responsible to the Agency's Executive Director and management board; Notes that, according to the Agency's reply, it is satisfied with the level of independence provided by the current framework, but it will consider, nevertheless, what changes could be introduced; calls on the Agency to report to the discharge authority on the developments in this regard; notes furthermore from the Agency that it launched the re-validation of its accounting systems in March 2018;
22. Welcomes the inquiry that the European Ombudsman opened into the arrangements that the Agency has in place for engaging with medicine producers before they apply for authorisations to market their medicines in the Union and welcomes the fact that all interested parties are invited to put forward their comments on this issue, especially since the Agency's income on fees and charges related to marketing authorisations increased by 14 million euros;
23. 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 (CHMP) perform both the role of consultant and 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;

Internal audit

24. Notes with concern that the Commission's Internal Audit Service carried out an audit of the Agency's 'Implementation of the pharmacovigilance fees Regulation' ⁽⁹⁾, which concluded that although the design of the management and the internal control system is adequate, there is a significant weakness, which was recorded as a 'very important' recommendation, regarding the Agency's management of the continuous deficit between income from pharmacovigilance fees and the related costs; notes that the Agency prepared an action plan which includes the ongoing evaluation by the Commission of the current fee and remuneration system; calls on the Agency to report to the discharge authority on the corrective actions taken to address the recommendations;

Other Comments

25. Notes that the Court issued an emphasis of matter paragraph in relation to the two London-based agencies, concerning the United Kingdom's decision to withdraw from the European Union; notes that the seat of the Agency will move to Amsterdam at the beginning of 2019 and that the Agency's accounts include provisions for related costs amounting to EUR 18 600 000; regrets that the lease agreement for the London based premises sets a rental period until 2039 with no exit clause; deeply regrets that the notes to the accounts disclose an amount of EUR 489 000 000 remaining rent until 2039, of which a maximum amount of EUR 465 000 000 corresponding to the lease period after the Agency's planned move to Amsterdam is disclosed as a contingent liability; urges the Agency and the European Commission to do their utmost to minimise the financial, administrative and operational impact of the unfavourable lease agreement and to report to the discharge authority on the developments in this regard;
26. Notes that the High Court of Justice of England and Wales issued on 20 February 2019 its judgment in the case brought by the Canary Wharf Group against the Agency on the lease of its London premises; regrets that the Court ruled that Brexit and its consequences are not a cause for terminating the contract, despite recognising that Brexit was not foreseeable by the parties when the contract was signed in 2011; observes however that the judgment confirms the possibility for the Agency to sublet or assign the premises in London subject to the landlord's consent; encourages the Agency to explore this possibility in order to find a satisfactory solution before the end of the first semester 2019;

⁽⁹⁾ Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use (OJ L 189, 27.6.2014, p. 112).

27. Acknowledges that the Agency established an operations and relocation preparedness task force to ensure that the Agency takes all the necessary steps to maintain the continuity of its business operations following the United Kingdom's withdrawal from the European Union and the Agency's transfer to the Netherlands; notes with satisfaction that in 2017, the Agency took several steps towards the relocation to Amsterdam, including an impact assessment, staff surveys, a dedicated recruitment and selection strategy following the United Kingdom's decision to withdraw from the European Union and preparations for the relocation of the Agency's data centres;
 28. Highlights that, according to the Agency, it requires significant resources to be redistributed for relocation tasks and that a shortage of human resources may result in challenges for the Agency to fulfil its core and legislative responsibilities; calls on the Agency to report to the discharge authority on any developments in that regard;
 29. Refers, for other observations of a cross-cutting nature accompanying its decision on discharge, to its resolution of 26 March 2019 ⁽³⁾ on the performance, financial management and control of the agencies.
-

⁽³⁾ Texts adopted, P8_TA(2019)0254. See page 361 of this Official Journal.