2016 discharge: European Medicines Agency (EMA)

2017/2154(DEC) - 18/04/2018 - Text adopted by Parliament, single reading

The European Parliament decided to **grant discharge** to the Director of the European Medicines Agency (EMA) in regard to the implementation of the agency's budget for the 2016 financial year and to approve the closure of the accounts for the financial year in question.

Noting that the Court of Auditors has stated that it has obtained reasonable assurances that the agency's annual accounts for the financial year 2016 are reliable and that the underlying transactions are **legal and regular**, Parliament adopted by 534 votes to 45 with 18 abstentions, a resolution containing a series of recommendations, which form an integral part of the decision on discharge and which add to the general recommendations set out in the resolution on performance, financial management and control of EU agencies:

Follow-up to the 2014 discharge: Members noted 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 dissemination of appropriate pharmacovigilance information to the Member States** and to the general public. They called on the agency to complete the corrective actions as soon as possible in 2018 and to report to the discharge authority on their implementation.

- **Agency's financial statements:** the European Medicines Agency's final budget for the financial year 2016 was EUR 308 422 000, representing an increase of 0.1 % compared to 2015. As a reminder, 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.
- **Reliability of the accounts:** 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. Members noted with regret that, although the matter was repeatedly raised with the Agency, no corrective action has been taken. They called on the Agency to implement corrective actions as soon as possible in 2018.
- **Legality and regularity of transactions:** irregularities concerned **corporate rate agreements** for the provision of accommodation for experts with 25 hotels in London without using a competitive procurement procedure. 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. The six corporate rate agreements and the related 2016 payments, amounting to some EUR 2.1 million are therefore irregular.
- **Budget and financial management:** 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. It was highlighted that agency was not allowed to create a 'Brexit' contingency reserve.
- **Human resources policy:** Members regretted that the **gender balance** had not been met, since the ratio is 69 % female to 31 % male. They stressed that the **staff cuts** imposed in recent years have meant a reduction in staff working on tasks that are actually funded by applicants' fees and not by the Union budget. Members observed with satisfaction that the agency put in place a health and safety group for consultation with staff. It also has a policy in place for protecting the dignity of the person and preventing any form of psychological or sexual harassment.

- **Prevention and management of conflicts of interests, transparency and democracy:** Parliament noted 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. 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. 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. Members emphasised the need to establish an independent body with sufficient budgetary resources to support **whistleblowers** wishing to disclose information on possible irregularities negatively impacting on the Union's financial interests, while ensuring their confidentiality is protected.

Impact of Brexit: Members stressed that the agency will be facing an additional workload and additional 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. They called on the Commission to provide **adequate staff and budgetary resources** in preparation for its relocation in 2019.

Parliament also proposed that the agency 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. They also stressed the need for the accelerated building approval so as to avoid any delays in the start of the construction of the new agency premises in Amsterdam. The agency has disclosed in its financial statements an estimated EUR 448 million in rent for the remaining rental period between 2017 and 2039 as a contingent liability, as the rental contract does not include any exit clause.