2016 discharge: European Medicines Agency (EMA)

2017/2154(DEC) - 19/09/2017 - Court of Auditors: opinion, report

PURPOSE: presentation of the EU Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2016, together with the Agency's reply.

CONTENT: in accordance with the tasks conferred on the Court of Auditors by the Treaty on the Functioning of the European Union, the Court presents to the European Parliament and to the Council, in the context of the discharge procedure, a Statement of Assurance as to the reliability of the annual accounts of each institution, body or agency of the EU, and the legality and regularity of the transactions underlying them, on the basis of an independent external audit.

This audit concerned, amongst others, the annual accounts of the European Medicines Agency (**EMA**). In brief, the Agency operates through a network and coordinates the scientific resources made available by the national authorities in order to ensure the evaluation and supervision of medicinal products for human or veterinary use.

Statement of assurance: pursuant to the provisions of Article 287 of the Treaty on the Functioning of the European Union (TFEU), the Court has audited:

- the annual accounts of the Agency, which comprise the financial statements and the reports on the implementation of the budget for the financial year ended 31 December 2016, and
- the legality and regularity of the transactions underlying those accounts.

Opinion on the reliability of the accounts: in the Court's opinion, the Agency's annual accounts present fairly, in all material respects, its financial position as at 31 December 2016 and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its Financial Regulation and the accounting rules adopted by the Commission's accounting officer.

Opinion on the legality and regularity of the transactions underlying the accounts: in the Court's opinion, the transactions underlying the annual accounts for the year ended 31 December 2016 are legal and regular in all material respects.

Emphasis of matter: without calling into question its opinion, the Court draws attention to the fact that the United Kingdom (UK) notified the European Council on 29 March 2017 of its decision to withdraw from the European Union. An agreement setting out the arrangements for its withdrawal will be negotiated. The provisional accounts and related notes of the Agency, which is located in London, were prepared using the limited information available at the date of signature (28 February 2017).

In view of upcoming decisions on the future location of the Agency, it has disclosed in its Financial Statements an estimated EUR 448 million rent for the remaining rental period between 2017 and 2039 as a contingent liability, as the rental contract does not include any exit clause. Moreover, 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. Furthermore, the Agency's 2016 budget was financed 95 % by fees from pharmaceutical companies and 5 % from European Union funds. A future decrease of the Agency's revenue resulting from the UK's decision to leave the EU is possible.

The report also makes a series of observations regarding the Agency, accompanied by the latter's response. The main observations may be summarised as follows:

The Court's observations:

- **legality of the transactions**: the Court noted that the Agency concluded 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.

The Agency's replies:

- **legality of the transactions**: the Agency noted the finding of the Court and, as discussed with the auditors, will identify and implement a solution for hotel bookings during 2017-2018. The Agency wants to highlight that the procedure subject to ECA's comment was put in place in order to minimise the administrative and financial burden of the Agency's delegates, simplify the organisation and guarantee an efficient running of their meetings. The rules regarding delegate reimbursements apply hotel cost ceilings approved by the Management Board and are in line with the European Commission. A procurement to address this matter is being prepared.

Lastly, the Court of Auditors' report contains a summary of the **Agency's key figures in 2016**:

Budget: EUR 305 million.

Staff: 768 including officials, temporary and contract staff and seconded national experts.