2017 discharge: European Medicines Agency (EMA)

2018/2185(DEC) - 18/09/2018

PURPOSE: presentation of the EU Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2017, together with the Agency's reply.

CONTENT: the Court of Auditors carried out the audit on 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 and reliability of the accounts

The Court considered that:

- the Agency's annual accounts present fairly, in all material respects, its financial position as at 31 December 2017 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;

- the transactions underlying the annual accounts for the year ended 31 December 2017 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 is currently being negotiated. The accounts and related notes of the Agency, which is located in London, were prepared using the information available at the date of signature (1 June 2018).

On 20 November 2017, the General Affairs Council of the European Union agreed to move the seat of the Agency to Amsterdam, The Netherlands. The removal to temporary premises is planned for the beginning of 2019 and the Agency's accounts include provisions for related costs amounting to EUR 18.6 million.

Moreover, the lease agreement for the Agency's current premises in London sets a rental period until 2039 with no exit clause. The notes to the accounts disclose an amount of EUR 489 million remaining rent until 2039, of which a maximum amount of EUR 465 million corresponding to the lease period after the Agency's planned move to Amsterdam is disclosed as a contingent liability.

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

The Court's observations

Financial management

Agencies should introduce a single solution for the electronic exchange and storage of information with third parties participating in public procurement procedures (e-procurement). As the same requirement exists for all EU Institutions, the Commission is developing a comprehensive IT solution covering all phases of public procurement procedures. The Commission launched tools for electronic invoicing (e-invoicing), for the electronic publication of documents related to contract notices (e-tendering) and for the electronic submission of tenders (e-submission). By the end of 2017, the Agency had introduced e-tendering for certain procedures, but not e-invoicing and e-submission.

On the management of consulting services, the Court noted the excessive use of consulting firms for external expertise. Control over project development and implementation was also inadequate and that projects were considerably delayed and costs were escalating.

Several measures were taken to improve the situation. The Agency is moving to the use of fixed price rather than time and means based consulting contracts, allowing for a better cost management.

The Agency's reply

Financial management

The Agency stated that by the end of 2017 the Agency had introduced e-tendering for all procedures above the directive threshold and email tender procedures for procedures below the directive threshold. The Agency has not introduced e-invoicing and e-submission, but in September 2017 the Agency signed a Memorandum of Understand with the European Commission for access to and the use of e-submission and is awaiting a date from the European Commission for the same.

Lastly, the Court of Auditors' report contains a summary of the Agency's key figures in 2017:

Budget

EUR 331 million.

Staff

766 including officials, temporary and contract staff and seconded national experts.