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COVER NOTE

From:	Mr Klaus-Heiner LEHNE, President of the European Court of Auditors
date of receipt:	28 November 2017
To:	Mr Märt KIVINE, President of the Council of the European Union
Subject:	Report on the annual accounts of the European Medicines Agency for the financial year 2016 together with the Agency's reply

Delegations will find attached the European Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2016.

This report is accompanied by the Agency's reply and will shortly be published in the *Official Journal of the European Union*.

Encl.: Report on the annual accounts of the European Medicines Agency for the financial year 2016 together with the Agency's reply.[1]

[1] In English only. The other languages of this report are available on the European Court of Auditors' website: http://eca.europa.eu/.

EUROPEAN
COURT
OF AUDITORS

Report on the annual accounts of the European Medicines Agency for the financial year 2016

together with the Agency's reply

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INTRODUCTION

1. The European Medicines Agency (hereinafter "the Agency", aka "EMA"), which is located in London, was established by Council Regulation (EEC) No 2309/93, which was replaced by Regulation (EC) No 726/2004 of the European Parliament and of the Council[1]. The Agency operates through a pan-EU 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.

2. ***Table 1*** presents key figures for the Agency[2]

TABLE 1: KEY FIGURES FOR THE AGENCY

	2015	**2016**
Budget (million euro)	304	305
Total staff as at 31 December[3]	775	768

Source: data provided by the Agency.

INFORMATION IN SUPPORT OF THE STATEMENT OF ASSURANCE

3. The audit approach taken by the Court comprises analytical audit procedures, direct testing of transactions and an assessment of key controls of the Agency's supervisory and control systems. This is supplemented by evidence provided by the work of other auditors and an analysis of management representations.

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[1] OJ L 214, 24.8.1993, p. 1, and OJ L 136, 30.4.2004, p. 1. In accordance with the latter Regulation, the Agency's original name, the European Agency for the Evaluation of Medicinal Products, was changed to the European Medicines Agency.

[2] More information on the Agency's competences and activities is available on its website: www.ema.europa.eu.

[3] Staff includes officials, temporary and contract staff and seconded national experts.

OPINION

4. We have audited:

(a) the accounts of the Agency which comprise the financial statements[4] and the reports on the implementation of the budget[5] for the financial year ended 31 December 2016, and

(b) the legality and regularity of the transactions underlying those accounts,

as required by Article 287 of the Treaty on the Functioning of the European Union (TFEU).

Reliability of the accounts

Opinion on the reliability of the accounts

5. In our opinion, the accounts of the Agency for the year ended 31 December 2016 present fairly, in all material respects, the financial position of the Agency at 31 December 2016, the results of its operations, its cash flows, and the changes in net assets for the year then ended, in accordance with its Financial Regulation and with accounting rules adopted by the Commission's accounting officer. These are based on internationally accepted accounting standards for the public sector.

Legality and regularity of the transactions underlying the accounts

Revenue

Opinion on the legality and regularity of revenue underlying the accounts

6. In our opinion, revenue underlying the accounts for the year ended 31 December 2016 is legal and regular in all material respects.

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[4] The financial statements comprise the balance sheet, the statement of financial performance, the cashflow statement, the statement of changes in net assets and a summary of significant accounting policies and other explanatory notes.

[5] The reports on implementation of the budget comprise the reports which aggregate all budgetary operations and the explanatory notes.

Payments

Opinion on the legality and regularity of payments underlying the accounts

7. In our opinion, payments underlying the accounts for the year ended 31 December 2016 are legal and regular in all material respects.

Responsibilities of management and those charged with governance

8. In accordance with Articles 310 to 325 of the TFEU and the Agency's Financial Regulation, management is responsible for the preparation and presentation of the accounts on the basis of internationally accepted accounting standards for the public sector and for the legality and regularity of the transactions underlying them. This responsibility includes the design, implementation and maintenance of internal controls relevant to the preparation and presentation of financial statements that are free from material misstatement, whether due to fraud or error. Management is also responsible for ensuring that the activities, financial transactions and information reflected in the financial statements are in compliance with the authorities which govern them. The Agency's management bears the ultimate responsibility for the legality and regularity of the transactions underlying the accounts.

9. In preparing the accounts, management is responsible for assessing the Agency's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting.

10. Those charged with governance are responsible for overseeing the entity's financial reporting process.

Auditor's responsibilities for the audit of the accounts and underlying transactions

11. Our objectives are to obtain reasonable assurance about whether the accounts of the Agency are free from material misstatement and the transactions underlying them are legal and regular and to provide, on the basis of our audit, the European Parliament and the Council or other respective discharge authorities with a statement of assurance as to the reliability of the accounts and the legality and regularity of the transactions underlying them. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit will always detect a material misstatement or non-compliance when it exists. These can arise from fraud or error and are considered material if,

individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these accounts.

12. An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the accounts and the legality and the regularity of the transactions underlying them. The procedures selected depend on the auditor's judgment, including an assessment of the risks of material misstatement of the accounts and of material non-compliance of the underlying transactions with the requirements of the legal framework of the European Union, whether due to fraud or error. In making those risk assessments, internal controls relevant to the preparation and fair presentation of the accounts and legality and regularity of underlying transactions, are considered in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of internal controls. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the management, as well as evaluating the overall presentation of the accounts.

13. For revenue, we verify the subsidy received from the Commission and assess the Agency's procedures for collecting fees and other income.

14. For expenditure, we examine payment transactions when expenditure has been incurred, recorded and accepted. Advance payments are examined when the recipient of funds provides justification for their proper use and the Agency accepts the justification by clearing the advance payment, whether in the same year or later.

15. In preparing this report and Statement of Assurance, we considered the audit work of the independent external auditor performed on the Agency's accounts as stipulated in Article 208(4) of the EU Financial Regulation[6].

Emphasis of matter

16. 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.

[6] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council (OJ L 298, 26.10.2012, p. 1).

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).

17. In view of upcoming decisions on the future location of the Agency, it has disclosed in its Financial Statements an estimated 448 million euro 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.

18. The comments which follow do not call the Court's opinion into question.

COMMENTS ON THE RELIABILITY OF THE ACCOUNTS

19. Since the introduction of a new IT accounting system in 2011, reporting on commitment workflow and consumption has not been sufficiently transparent. Although the matter was repeatedly addressed to the Agency, no corrective action has been taken.

COMMENTS ON THE LEGALITY AND REGULARITY OF TRANSACTIONS

20. 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 2,1 million euro are therefore irregular.

COMMENTS ON INTERNAL CONTROL

21. In 2014 the Commission, on behalf of more than 50 EU Institutions and bodies (including the Agency) signed a framework contract with one contractor for the acquisition of software, licences and the provision of related IT maintenance and consultancy. The framework contractor acts as an intermediary between the Agency and suppliers that can

address the Agency's needs. For these intermediary services the framework contractor is entitled to uplifts of two to nine percent of the suppliers' prices. In 2016, total payments to the framework contractor amounted to 8,9 million euro. The Agency did not systematically check prices and uplifts charged with the suppliers' quotes and invoices issued to the framework contractor.

COMMENTS ON SOUND FINANCIAL MANAGEMENT AND PERFORMANCE

Human resources management

22. Since 2014 the Agency has undergone two major re-organisations including the internal re-allocation of top and middle management positions. The re-allocation of key staff in the area of IT and administration was not successful, causing material risk of instability to the Agency and its operations. Moreover, there is no system in place to analyse skills availability, identify gaps and to recruit and allocate appropriate staff.

Consultancy

23. In addition to the annual audit work carried out for all agencies, the Court did an analysis of the Agency's use of consulting services in relation to two major projects.

24. The Agency has been tasked by Parliament and Council with the implementation of the Regulations on Pharmacovigilance (1027/2012) and Clinical Trials (536/2014) which necessitate the establishment of complex pan-EU network systems. This requires extensive technical IT development and participation, as well as input from multiple stakeholders, and in particular Member States.

25. These tasks were assigned to the Agency when it was expected to reduce staff in accordance with the Inter-Institutional Agreement on budgetary discipline adopted on 2 December 2013. There was no increase in the Agency's staff establishment plan that would enable it to built-up the necessary expertise in the areas of business and IT development.

Extensive us of external consultants

26. Given that the Agency had just 13 staff employed in the I-Delivery Department, it engaged consulting companies in the areas of business analysis, information technology,

project management and quality assurance. In the second quarter of 2016 the Agency had 131 consultants on site and an additional 60 consultants off site.

27. The Agency therefore is critically dependent on external expertise since the start of the projects, yet there is no policy in place to govern the use of consultants. For instance, the profiles the Agency's own staff should occupy are not defined (Project Management, Business Analysis, Business Architects, Solution Architects, Data Architects etc). Such profiles have at times been assigned to external consultants.

Inadequate control over project development and implementation

28. When the Agency was entrusted with the new tasks in 2012 and 2014 it did not have an adequate methodology in place to manage projects of such scale. A new methodology was introduced in 2014 which had to be considerably refined in September 2016.

29. In a number of instances alterations from the planned activities or approach occurred before they were authorised via a formal change request. Such practice not only impairs management's ability to supervise and monitor project development and implementation but can also undermine projects' coherence.

30. Until mid-2016 all external consultants were engaged on the basis of time and means contracts although project deliverables were clearly defined. Also, a considerable part of the consulting engagements was carried out in another Member State since all London-based external resources had been exhausted. This limited the Agency's ability to monitor the implementation of the projects in a timely manner. Quality issues identified upon receipt of deliverables required rectification for which additional cost was charged to the Agency.

Delay and escalating cost

31. The Agency has experienced delays and escalating costs in developing the systems. Frequent changes in project scope, budget and deadlines were due mainly to evolving system requirements taking into account changing needs of Member States[7]. There is no

[7] Telematics governance bodies where Member States are represented to elaborate and endorse requirements of future IT systems.

certainty yet regarding final costs and go-live dates. See examples in the table below for two major projects:

	Initial date for GO-LIVE	Current planned date for GO-LIVE	Initial Budget	Budget as at 31 October 2016
Eudravigilance Database Adverse Drug Reactions	Q3 2015	Q4 2017	3,7 million	14,3 million
Clinical Trials & EU Database	Q1 2017	Q3 2018	6,1 million	24,3 million

OTHER COMMENTS

32. The founding Regulation requires an external evaluation of the Agency and its operations by the Commission every ten years. The last evaluation report was issued in 2010. Such a long time span does not ensure timely performance feedback to stakeholders.

FOLLOW-UP OF PREVIOUS YEARS' COMMENTS

33. An overview of the corrective action taken in response to the Court's comments from previous years is provided in the ***Annex***.

This Report was adopted by Chamber IV, headed by Mr Baudilio TOMÉ MUGURUZA, Member of the Court of Auditors, in Luxembourg at its meeting of 19 September 2017.

For the Court of Auditors

Klaus-Heiner LEHNE

President

Annex

Follow-up of previous years' comments

Year	Court´s comments	Status of corrective action (Completed / Ongoing / Outstanding / N/A)
2014	The Agency's fee regulation provides due dates for the collection of fees from applicants and the Agency's related payments to National Competent Authorities[1]. These due dates were not respected for most of the transactions audited by the Court.	**Ongoing (fee collection)** **Completed (payments to NCAs)**
2014	In 2014, the Agency carried out an administrative procedure against its Information, Communication and Technology (ICT) manager. Significant weaknesses in management control were reported, implying considerable operational and financial risks to the Agency. An action plan to address the issue was established and implemented. However, the effectiveness of the measures taken has yet to be evaluated by the Agency.	**Ongoing**
2014	One of the Agency's tasks is to distribute appropriate pharmacovigilance information to Member States and to the general public. This information is collected from individual national authorities and verified with the pharmaceutical companies concerned. However, the Agency is largely dependent on controls and inspections carried out by Member States' authorities. These determine the completeness and accuracy of information disseminated to the public.	**Ongoing**

[1] Agency's fee regulation, Articles 10(1) and 11(1).

THE AGENCY'S REPLY

19. The Agency takes note of the Court's comments. Following the referendum, the Agency has set up a dedicated task force to assess the impact and to prepare the Agency for relocation. The task force and sub-groups focus on different aspects of the impact and relocation: scientific procedures and work of scientific committees; procurements; impact on IT systems; impact on human and financial resources; staff relocation support; move; business continuity arrangements. The challenge for robust budgetary forecasting remains the high level of unknown factors, e.g. location of new seat and associated operating cost environment; conditions offered by new host; level of infrastructure investment needed to enable the Agency to operate effectively; staff loss as a consequence of relocation. It is important to recognise that only once the seat agreement is concluded can detailed financial implications be properly assessed.

21. The IT accounting system has a solid and reliable commitment workflow process that provides assurance as to the legality and regularity of the individual transactions underlying the accounts and the Agency monitors budget consumption via a robust budget monitoring process. However, the complexity of the system and the significant number of transactions processed every year renders the set-up of a fully transparent reporting system adequate to the ECA needs expensive and complicated. The Agency effort will continue in 2017, although it must be noted that the same team will also be engaged in Brexit preparedness activities.

22. The Agency notes 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.

23. In line with ECA's view on the matter of introducing a systematic check, the Agency will introduce systematic checks for every quotation above €135,000 from 1-Jan-2018.

24. In 2014 the Agency had to restructure its IT Division due to some exceptional circumstances. After the reorganisation, the productivity was significantly recovered and enhanced. Organisational changes took place in the administration division, following retirement and departure of senior staff, with the objective to streamline the reporting chain, the specialisation and the efficiency of the various departments and services involved, and to align the organisation to the requirements of the financial regulation on programming. The Agency considers that no instability was suffered by the Agency due to organisational changes.
The HR Strategy of 2017 to 2020 sets out objectives for a more structured and systematic approach in relation to skills assessment, including the introduction of a tool to improve the efficiency in skills and competency mapping for gap-analysis and as a support for its recruitment activities. The implementation for the first phase is underway.

25. The Agency takes the note of the comment.

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27. The Agency takes the note of the comment.

28. The Agency takes the note of the comment.

29. The Agency wishes to re-iterate that, although EMA does not have a documented policy governing the use of consultants, in IT the practice since 2016 is to employ staff for sensitive profiles (e.g. project manager) or to use consultants for such profiles when they are closely supervised by senior staff of the same profile. The EMA will document this policy.

30. Project management methodologies were in place from the initiation of all projects but significant new tasks were assigned to the Agency without a corresponding increase in resources that would have allowed the building-up of the necessary know-how and capacity in the areas of IT and business development. During the period since these projects were launched the Agency has undertaken a fundamental review and reorganisation of both IT

governance and project management methodology. The Agency now works under the gated methodology for more than three years and continuously improves it.

31. The changes in planned activities were always subject of detailed internal discussions and agreement at established governance bodies such as the EU Portal and Database Project Board and Clinical Trials Programme Board. Furthermore, a regular programme and project reporting was in place allowing oversight of proposed changes in approach. In a number of cases the Executive Board made agreements in principle, before the individual boards could then process the agreed steps.

32. Before mid-2016, EMA was limited by existing IT framework contracts which did not allow for extensive use of fixed price contracts. The Agency took a carefully considered decision to use external contractors to leverage on established contractor's offsite teams (as opposed to recruiting individual contractors onsite). Monitoring on site was undertaken by staff (project managers, technical managers). Monitoring off site in another Member State was undertaken by establishing remote monitoring using shared workspace and remote meetings and sending staff off site when necessary. Going forward: since mid-2016 onwards, a new framework contract was signed allowing for significantly more extensive use of fixed price contracting. Since mid-2016 all large IT projects are delivered with fixed price contracts.

33. As recognised by the Court, changes in project scope, budget and deadlines were due mainly to evolving system requirements taking into account evolving needs of Member States. These are large, complex systems required to serve the business operational requirements, and enable the legal obligations, of Marketing authorisation holders, clinical trial sponsors and Member States and not only, or at all, the operational activities of the Agency itself.

34. The Commission is currently preparing the next evaluation to be conducted in the period 2017-2018. It should also be noted that, taking into consideration the specificities of the Agency, there are also reporting and auditing requirements on the operation of specific pieces of legislation (e.g. paediatric, pharmacovigilance, advanced therapy medicinal

products regulations) implemented by the Agency. These supplement the evaluation work referred to above.