European Parliament
2019-2024

TEXTS ADOPTED

P9_TA(2021)0181

2019 discharge: European Medicines Agency

1. European Parliament decision of 28 April 2021 on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2019 (2020/2157(DEC))

The European Parliament,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2019,

– having regard to the Court of Auditors' annual report on EU agencies for the financial year 2019, together with the agencies' replies[1],

– having regard to the statement of assurance[2] as to the reliability of the accounts and the legality and regularity of the underlying transactions provided by the Court of Auditors for the financial year 2019, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of 1 March 2021 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2019 (05793/2021 – C9-0054/2021),

– having regard to Article 319 of the Treaty on the Functioning of the European Union,

– having regard to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012[3], and in particular Article 70 thereof,

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1 OJ C 351, 21.10.2020, p. 7. ECA annual report on EU agencies for the 2019 financial year: https://www.eca.europa.eu/Lists/ECADocuments/AGENCIES_2019/agencies_2019_EN.pdf.

2 OJ C 351, 21.10.2020, p. 7. ECA annual report on EU agencies for the 2019 financial year: https://www.eca.europa.eu/Lists/ECADocuments/AGENCIES_2019/agencies_2019_EN.pdf.

3 OJ L 193, 30.7.2018, p. 1.

– having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 68 thereof,

– having regard to Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[2], and in particular Article 105 thereof,

– having regard to Articles 32 and 47 of Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council[3],

– having regard to Rule 100 of and Annex V to its Rules of Procedure,

– having regard to the opinion of the Committee on the Environment, Public Health and Food Safety,

– having regard to the report of the Committee on Budgetary Control (A9-0073/2021),

1. Grants the Executive Director of the European Medicines Agency discharge in respect of the implementation of the Agency's budget for the financial year 2019;

2. Sets out its observations in the resolution below;

3. Instructs its President to forward this decision, and the resolution forming an integral part of it, to the Executive Director of the European Medicines Agency, the Council, the Commission and the Court of Auditors, and to arrange for their publication in the *Official Journal of the European Union* (L series).

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 122, 10.5.2019, p. 1.
3 OJ L 328, 7.12.2013, p. 42.

2. European Parliament decision of 28 April 2021 on the closure of the accounts of the European Medicines Agency for the financial year 2019 (2020/2157(DEC))

The European Parliament,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2019,

– having regard to the Court of Auditors' annual report on EU agencies for the financial year 2019, together with the agencies' replies[1],

– having regard to the statement of assurance[2] as to the reliability of the accounts and the legality and regularity of the underlying transactions provided by the Court of Auditors for the financial year 2019, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of 1 March 2021 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2019 (05793/2021 – C9-0054/2021),

– having regard to Article 319 of the Treaty on the Functioning of the European Union,

– having regard to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012[3], and in particular Article 70 thereof,

– having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[4], and in particular Article 68 thereof,

– having regard to Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[5], and in particular Article 105 thereof,

– having regard to Articles 32 and 47 of Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies

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1 OJ C 351, 21.10.2020, p. 7. ECA annual report on EU agencies for the 2019 financial year: https://www.eca.europa.eu/Lists/ECADocuments/AGENCIES_2019/agencies_2019_EN.pdf.

2 OJ C 351, 21.10.2020, p. 7. ECA annual report on EU agencies for the 2019 financial year: https://www.eca.europa.eu/Lists/ECADocuments/AGENCIES_2019/agencies_2019_EN.pdf.

3 OJ L 193, 30.7.2018, p. 1.

4 OJ L 136, 30.4.2004, p. 1.

5 OJ L 122, 10.5.2019, p. 1.

referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council[1],

– having regard to Rule 100 of and Annex V to its Rules of Procedure,

– having regard to the opinion of the Committee on the Environment, Public Health and Food Safety,

– having regard to the report of the Committee on Budgetary Control (A9-0073/2021),

1. Approves the closure of the accounts of the European Medicines Agency for the financial year 2019;

2. Instructs its President to forward this decision to the Executive Director of the European Medicines Agency, the Council, the Commission and the Court of Auditors, and to arrange for its publication in the *Official Journal of the European Union* (L series).

[1] OJ L 328, 7.12.2013, p. 42.

3. European Parliament resolution of 29 April 2021 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 2019 (2020/2157(DEC))

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 2019,

– having regard to Rule 100 of and Annex V to its Rules of Procedure,

– having regard to the opinion of the Committee on the Environment, Public Health and Food Safety,

– having regard to the report of the Committee on Budgetary Control (A9-0073/2021),

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 2019 was EUR 346 762 000, representing an increase of 2,66 % compared to 2018; whereas the Agency is a fee-funded agency, with 85,70 % of its 2019 revenue stemming from fees paid by the pharmaceutical industry for services provided;

B. whereas the Court of Auditors (the 'Court'), in its report on the annual accounts of the Agency for the financial year 2019 (the 'Court's report'), states that it has obtained reasonable assurance that the Agency's annual accounts are reliable and that the underlying transactions are legal and regular;

Budget and financial management

1. Notes with satisfaction that budget monitoring efforts during the financial year 2019 resulted in a budget implementation rate of 98,56 %, representing an increase of 9,42 % compared to 2018; notes that the payment appropriations execution rate was 83,05 %, representing an increase of 9,41 % compared to 2018;

2. Notes that the Agency is a fee-funded agency, with 85,70 % of its 2019 revenue stemming from fees paid by the pharmaceutical industry, 14,29 % stemming from the Union budget and 0,01 % stemming from external assigned revenue;

Performance

3. Notes that the Agency uses several key performance indicators, including a combination of operational, management and governance indicators and communication and stakeholder indicators to measure its workload volumes, its work programme implementation and its stakeholder satisfaction, and to assess the added value provided by its activities; notes furthermore that the Agency uses a budget planning and monitoring methodology to enhance its budget management; calls on the Agency to evaluate the complexity and transparency of those key performance indicators and introduce unifications and simplification if needed;

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[1] OJ C 391, 18.11.2019, p. 51.

4. Notes that the Agency cooperates with other agencies on joint scientific outputs and exchanges scientific data; recognises furthermore that the Agency continues to have formal working arrangements with the European Centre for Disease Prevention and Control, the European Food Safety Authority, the European Chemicals Agency and the European Monitoring Centre for Drugs and Drug Addiction in order to have mutual consultation in areas of common interest; notes that the Agency participates in joint procurement with other agencies and in particular with other agencies based in the Netherlands; notes further that the Agency also took part in procurement services managed by the Commission;

5. Notes that the Internal Audit Service carried out a risk assessment to prepare its audit plan for 2020-2022;

6. Is concerned that the Regulation (EC) No 726/2004 has not yet been aligned with the common approach; is concerned with the length of the evaluation frequency of 10 years for the Agency;

7. Calls on the Agency to continue to develop its synergies and increase cooperation and the exchange of good practices with other agencies of the Union with a view to improving efficiency (human resources, building management, IT services and security);

8. Stresses the importance of increasing the digitalisation of the Agency in terms of internal operations and management procedures; stresses the need for the Agency to continue to be proactive in this regard in order to avoid a digital gap between the agencies at all costs; draws attention, however, to the need to take all the necessary security measures to avoid any risk to the online security of the information processed;

9. Notes that, according to Special Report No 22/2020 of the Court entitled Future of EU agencies - Potential for more flexibility and cooperation, the Agency needs to improve its cooperation with the Commission; calls on the Agency and the Commission to report back on the developments in this regard to the discharge authority;

10. Emphasises the important role of the Agency in protecting and promoting public and animal health by assessing and supervising medicines for human or veterinary use;

11. Highlights the fact that, in 2019, the Agency recommended 81 new medicines for marketing authorisation (66 for human use and 15 for veterinary use), and that those new medicines included 35 new active substances (30 for human use and 5 for veterinary use);

12. Notes that phase 4 of the business continuity plan started on 1 January 2019, in order to safeguard the core activities of the Agency;

Staff policy

13. Notes that, on 31 December 2019, the establishment plan was 98,65 % implemented, with 583 temporary agents appointed out of 591 temporary agents authorised under the Union budget (compared to 591 authorised posts in 2018); notes that in addition 199 contract agents and 31 seconded national experts worked for the Agency in 2019;

14. Reiterates its concern about the lack of gender balance among the Agency's senior management (19 men and 11 women) and on the management board (25 men and 13 women); asks the Agency to ensure that there is better gender balance in the future; asks

the Commission and the Member States to take into account the importance of ensuring gender balance when appointing members to the Agency's management board;

15. Notes that according to the 2018 follow-up report and the Court's 2019 report the Agency has still not fully implemented last year's recommendation on the use of external consultants; notes however that the Agency is committed to using such consultants only to enhance its delivery capacity if and when necessary; calls on the Agency to complete the implementation of that recommendation;

16. Is concerned that, according to Special Report No 22/2020 of the Court, the Agency struggles to recruit staff with the necessary technical expertise, and in order to compensate for a shortage of posts or national experts, the Agency increasingly outsources core tasks to private contractors, on whom it may then become dependent; calls on the Commission to examine the situation carefully and to provide the Agency with the necessary means to recruit the necessary staff; calls on the Commission to report back to the discharge authority on this matter;

17. Is concerned that, according to the Court's report, there were 119 on-site consultants providing services at the Agency's premises, employed by a number of providers, some of them from other Member States and some based in the Netherlands, and that the Agency was unable to confirm in relation to the temporary-work agency staff providing services on its premises whether they qualified for posted worker status under the provisions of Dutch law concerning the transposition of Directive 96/71/EC[1] and Directive 2014/67/EU[2] ; calls on the Agency to investigate and resolve that issue;

18. Notes that, according to the Court's report, to facilitate the transition from London to Amsterdam, the Agency granted an additional travel allowance to each member of staff who relocated to Amsterdam, and to the members of their household, which amounted to EUR 1 227 for each person, which was calculated as a flat-rate amount based on the price of a business-class ticket instead of an economy-class fare as stated in the Staff Regulations; notes that the Agency paid both the statutory allowance and this exceptional travel allowance to 481 of the Agency's members of staff and 524 members of their households, which in total amounted to a disbursement of EUR 1 263 305, compared to EUR 30 562 had only the statutory allowance been applied, the total amount expected to be spent on the exceptional travel allowance is EUR 1 477 743;

19. Notes the efforts made to improve the staff's well-being, especially as regards counselling services, sports activities and a well-being learning programme;

20. Is concerned about the large size of the management board of the Agency, which makes decision making difficult and generates considerable administrative costs;

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1 Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services (OJ L 18, 21.1.1997, p. 1).

2 Directive 2014/67/EU of the European Parliament and of the Council of 15 May 2014 on the enforcement of Directive 96/71/EC concerning the posting of workers in the framework of the provision of services and amending Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ('the IMI Regulation') (OJ L 159, 28.5.2014, p. 11).

21. Encourages the Agency to pursue the development of a long term human resources policy framework which addresses work-life balance, lifelong guidance and career development, gender balance, teleworking, geographical balance and recruitment and integration of people with disabilities;

22. Notes that the Agency has adopted a policy on protecting the dignity of the person and preventing harassment; takes note that one alleged harassment case was reported and investigated in 2019 under the formal procedure;

23. Acknowledges the impact of the United Kingdom's withdrawal from the European Union on the activities of the Agency and the resulting additional expenditure, amounting to EUR 51,44 million, including the staff, office and workspace costs related to the relocation of the Agency from London to Amsterdam; welcomes the extent to which the quality and continuity of the operations of the Agency were maintained whilst undertaking the relocation;

Sustainability

24. Welcomes the efforts made by the Agency to create an environmentally friendly workplace and all the measures taken by the Agency to reduce its carbon footprint, its energy consumption and to develop a paperless workflow;

25. Welcomes the fact that the Agency's new building which it occupies since January 2020 is highly energy efficient and provided with electricity originating from 100% renewable energy (windmills and solar panels);

26. Invites the Agency, with regard to its newly established headquarters, to pay due attention to the energy mix of its sources of electricity and encourage the procurement of electricity generated by renewable energy, as well as to adopt all possible environmentally friendly measures and solutions;

Procurement

27. Notes that the e-submission tool has now also been successfully implemented and is in use since early 2019, and that the e-invoicing tool is being implemented; calls on the Agency to report on the status of its implementation;

28. Notes that in 2019 the Agency conducted procurement procedures for the necessary contracts for the permanent building in Amsterdam, such as the procurement of a new medical service provider in its new premises;

29. Notes that, according to the Court's report, the Agency launched in 2019 a procurement procedure which covered the supply of printers, and the management of the goods loading bay at the Agency's new premises in Amsterdam, that those items were unrelated but nevertheless combined into a single lot for tender, for an estimated total amount of EUR 6 200 000 over a maximum period of six years; notes, that according to the Court's report, only two offers were received for this tender; notes and supports the Court's position that contracting authorities must divide contracts into lots to facilitate broad competition and to allow bidders equal access to procurement procedures;

30. Notes that, according to the Court's report, the Agency concluded in 2019 a framework contract with three companies for the supply of temporary workers, and that the combined

maximum value of the contract was EUR 15 450 000; further notes that, according to the tender specifications, the price element had a weighting factor of 40 % and that it was stipulated in the specifications that that element must include an all-inclusive hourly rate-conversion factor for application to the gross hourly remuneration of the temporary workers in specific staff categories; notes with concern that the Agency did not request an estimate of the gross staff cost for the interim workers in each requested staff category, which would have put the Agency in a better position to evaluate whether the service provider's mark-up or gross profit was reasonable in relation to similar contracts; demands that the Agency improves its procurement and planning processes, particularly with regard to the temporary and external staffing solutions;

Prevention and management of conflicts of interest and transparency

31. Acknowledges the Agency's existing measures and ongoing efforts to secure transparency to prevent and manage conflicts of interest, and to provide whistleblower protection; notes that in 2019 no internal whistleblowing case was reported, however, 20 reports of external whistleblowing cases were received; notes that 24 cases were closed, of which 13 cases were opened in 2019 and 11 during the previous years, seven cases are still ongoing; calls on the Agency to report to the discharge authority on the progress in those cases;

32. Asks the Agency to make sure the departments responsible for human resources and ethics guidelines ensure implementation of conflict of interest prevention and whistleblower protection policies;

33. Underlines that post-public employment and 'revolving door' conflict-of-interest situations are a problem common to many bodies and agencies across the Union;

34. Calls on the Agency to implement the recommendations of the European Ombudsman in its decision in case 2168/2019/KR on the European Banking Authority's decision to approve the request by its executive director to become CEO of a financial lobby group, in particular by ensuring, where necessary, that the option of forbidding its senior staff from taking up certain positions after their term-of-office is invoked; setting out criteria for when it will forbid moves of staff to the private sector; to inform applicants for senior posts in the Agency of the criteria when they apply; and to put in place internal procedures so that once that a member of its staff moves to another job, their access to confidential information is cut off with immediate effect;

35. Notes that, in 2019, no case of conflict of interest was reported by the Agency and that the Agency published the conflicts of interest declarations of its management board members and its senior management; notes with satisfaction that the Agency published the CVs of its management board members, senior management and of its external and in-house experts;

36. Underlines the fact that the current ethical framework applying to institutions and agencies of the Union suffers from considerable drawbacks due to its fragmentation and lack of coordination between existing provisions; highlights that those issues should be addressed by setting up a common ethical framework which ensures the application of high ethical standards for all institutions and agencies of the Union;

37. Underlines that certain officials fill in declarations of absence of conflicts of interest and provide self-assessments with regard to respect for ethical standards; highlights, however,

that such self-declarations and self-assessments are not sufficient and that additional scrutiny is therefore needed;

Internal controls

38. Notes that the Internal Audit Service met with the Agency to perform a risk assessment exercise leading to the three-year strategic internal audit plan for 2020-2022, and that the Internal Audit Service selected 'HR and Ethics', 'IT governance and portfolio management' and 'the management of meetings for Agency's committees', as the three main audit topics for the coming years;

39. Regrets that the Internal Audit Service did not carry out any audit in 2019;

40. Notes that, in 2019, the Agency's audit function carried out audit activities and associated tasks in line with the Agency's annual audit plan adopted by the management board in December 2018; notes that the Agency's audit function performed three audits, one legally required pharmacovigilance audit and two consultancy engagements; further notes that some audits planned for 2019 were postponed due to the relocation of the Agency to the Netherlands;

Other comments

41. Notes that the Court issued an emphasis of matter paragraph as regards note 3.1.3 of the Agency's provisional accounts, which describes the uncertainty of the lease agreement for the Agency's previous premises in London which lasts until 2039, with no provision for early termination; notes that the Agency moved to Amsterdam on 30 March 2019; further notes that in 2019 the Agency reached an agreement with its landlord to sublet its former office premises to a subtenant, under conditions that are consistent with the terms of the head lease, and that the sublease term lasts until the expiry of the Agency's lease in 2039; notes from the Court's report that, since the Agency remains a party to the rental contract, the Agency could be held liable for the entire amount remaining payable under the rental contract if the subtenant fails to meet its obligations, further notes that, as of 31 December 2019, the total estimated outstanding rent, associated service charges and landlord insurance to be paid by the Agency until the end of the lease term amounted to EUR 417 000 000;

42. Notes the emphasis of matter paragraph in the Court's report about the lease agreement which lasts until 2039, with no provision for early termination; welcomes the fact that, in July 2019, the Agency reached an agreement with its landlord and managed to sublease its former office premises with effect from July 2019, until the expiry of the Agency's lease; notes with concern that, since the Agency remains a party to the rental contract, it could be held liable for the entire amount remaining payable under that contract if the subtenant fails to meet its obligations, but welcomes the fact that a solution has been found;

43. Notes that, according to the Agency's follow-up report, the Agency's management board supports the discharge authority's observations concerning the Agency's liabilities arising in connection with the United Kingdom's withdrawal from the Union, and as regards the carrying out of commercial activities in a third country; notes further that, according to the Agency's replies to the Court's report, the Agency and its management board are concerned that, instead of focusing its full efforts on its mission of protecting and promoting public health, the Agency now must manage commercial property in a third

country, thereby diverting its human and financial resources from its public health responsibilities;

44. Welcomes the efforts of the Agency to strengthen its policies on transparency in relation to drugs and vaccines against COVID-19; notes that the authorisation process for a vaccine against COVID-19 will require a speedy and transparent process within the Agency; notes that specific attention should be paid to the transparency of data from clinical trials as regards such vaccines; welcomes the decision of the Agency to publish the clinical study reports of drugs and vaccines against COVID-19 within three days of marketing authorisation; encourages the Agency to publish data from clinical trials before marketing authorisation and failing that, in a timely manner; calls on the Agency to request that the sponsors of clinical trials make their clinical trial protocols public before marketing authorisation;

45. Points out that a complex approach is needed in order to make the website of the institutions of the Union accessible to persons with all kinds of disabilities as provided for in Directive (EU) 2016/2102[1], including as regards the availability of national sign languages; suggests that organisations representing disabled persons be involved in that process;

46. Notes the efforts made to increase the Agency's cyber security and data protection; is, however, concerned by recent media reports that sensitive internal Agency documents were stolen by hackers and published on the dark web, as well as by reports of the Agency being the subject of cyberattacks; urges the Agency to take comprehensive measures for its cybersecurity to avoid such incidents in the future;

47. Calls on the Agency to continue increasing the level of transparency around its activities; in particular calls on the Agency to resume as soon as possible its policy on the publication of clinical data for medicinal products for human use ('Policy 0070') which was suspended in December 2018 and has still not been reinstated today;

48. Notes with concern that the Agency still does not authorise requests for access to documents via email and regrets that long delays of more than a year are the norm in terms of answering those requests; calls on the Agency to publicly set, and comply with, clear timeframes for responding to such requests from now on;

49. Reminds the Agency that it is urgent that Regulation (EU) No 536/2014[2] is applied; recalls that this will only be possible with the launch of the fully functioning clinical trials information system which must not be further delayed; calls on the Agency to include a fully public monitoring dashboard in the clinical trials information system that allows the public to monitor and compare the performance of national competent authorities and clinical trials sponsors, including the timely discharge of their various obligations;

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1 Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies (OJ L 327, 2.12.2016, p. 1).

2 Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

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50. Refers, for other observations of a cross-cutting nature accompanying its decision on discharge, to its resolution of 29 April 2021[1] on the performance, financial management and control of the agencies.

[1] Texts adopted, P9_TA(2021)0215.