Official Journal
of the European Union

EN
L series

2024/2307

10.10.2024

RESOLUTION (EU) 2024/2307 OF THE EUROPEAN PARLIAMENT

of 11 April 2024

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 2022

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 2022,

— 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 (A9-0133/2024),

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 2022 was EUR 421 815 000, representing an increase of 11,23 % compared to 2021; whereas the Agency is a fee-funded agency, with approximately 88 % of its 2022 revenue stemming from fees derived from the evaluation of medicines and other business-related activities, and 12 % stemming from the Union budget and miscellaneous income;

B. whereas the Court of Auditors (the 'Court') in its report on the annual accounts of the Agency for the financial year 2022 (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;

C. whereas with regard to the Agency's procurement sector, no issues requiring corrective actions were reported for 2022, nor are there ongoing or outstanding corrective actions from previous years' audits and assessments;

Budget and financial management

1. Notes that budget monitoring efforts during the financial year 2022 resulted in a budget implementation rate of current year commitment appropriations of 96,80 %, representing a decrease of 0,42 % compared to 2021; regrets that the current year payment appropriations execution rate was 71,48 %, representing a decrease of 0,88 % compared to 2021;

2. Observes that for one audited payment of EUR 2 million, the Agency authorised the related budgetary commitment only after the legal commitment was accepted; recalls that this goes against Article 73(2) of the Agency's Financial Regulation; calls on the Agency to take immediate action and to implement measures to ensure that all financial transactions are in compliance with the Agency's Financial Regulation;

3. Recalls that potential liabilities arising, until 2039, from the lease on the Agency's former office premises in London remain an ongoing issue; notes with concern that, on 31 December 2022, the total estimated outstanding rent, associated service charges and landlord insurance to be paid by the Agency up to the end of the lease term was EUR 366 million**,** that is approximately EUR 23 million annually; notes that in July 2019, the Agency reached an agreement with its landlord, and sublet its former premises to a subtenant with effect from July 2019, under conditions that are consistent with the terms of the head lease; acknowledges that the term of the sublease lasts until the Agency's lease expires in June 2039 and that, since the Agency remains a party to the head lease, it could be held liable for the entire amount remaining payable under the contractual obligations of the head lease, if the subtenant fails to meet its obligations; draws attention to another element highlighted in the Agency's accounts, namely the uncertainties surrounding the financial performance of the subtenant's ultimate parent company as a result of the deterioration of its credit rating and the recent debt restructuring, which led to stopping of its payment; takes note that the Agency and its Management Board are concerned that the Agency, instead of focusing its full effort on its mission of protecting and promoting public health, now must also manage commercial property in athird country, diverting its human and financial resources from its public health responsibilities in relation to Union citizens; is aware that, on 11 January 2024, Parliament's Committee on Budgets held an exchange of views with the Agency regarding the potential amendment to the Agency's sublease for the Agency's former premises in London; insists on the need for a political decision in order to secure a long-term resolution of this issue; insists that while a long-term resolution is being pursued, a short-term measure should be found and deployed to address and contain the problem, given that the subtenant continues to fail to pay its rent;

[1] OJ C 489, 22.12.2022, p. 7.

Performance

4. Notes that the Agency in 2022 reported on 41 performance indicators, estimating an implementation rate of 92,60 %; notes that in 2022 the Agency leveraged its position as chair of the International Coalition of Medicines Regulatory Authorities to make progress with regard to the work on the harmonisation of international regulatory systems; observes that it has also delivered the implementation of three major pieces of legislation (Regulation (EU) No 536/2014 of the European Parliament and of the Council ([2]), Regulation (EU) 2019/6 of the European Parliament and of the Council ([3]) and the extended mandate in Regulation (EU) 2022/123 of the European Parliament and of the Council ([4])) and progress work on data governance;

5. Welcomes the fact that, on 1 March 2022, the Agency's mandate was extended with the entry into force of the Regulation (EU) 2022/123 reinforcing its role in crisis preparedness and management of medicinal products and medical devices; notes that that Regulation required the Agency to set up new bodies, such as the Medicine Shortages Steering Group and the Emergency Task Force (ETF) and, in addition, the Agency took on the management of the expert panels on medical devices which were transferred to the Agency from the Commission's Joint Research Centre; notes furthermore that the Agency, under Regulation (EU) 2022/123, is responsible for monitoring events that may lead to a crisis, reporting and coordinating Union responses to shortages of critical medicines, medical devices and *in vitro* diagnostics during a crisis;

6. Highlights the fact that other key achievements in 2022 include the approval of two new vaccines and two COVID-19 treatments, the ETF recommended the temporary use of the US-approved monkeypox vaccine Jynneos for Monkeypox to support vaccination efforts by national EU authorities, alongside an extension of the use of Imvanex to also protect adults from monkeypox; takes note that additionally, the Agency collaborated with Erasmus University Medical Center in Rotterdam to establish the Coordination Centre for the Data Analysis and Real World Interrogation Network (Darwin EU®), serving as a pathfinder for the proposed Regulation for a European Health Data Space (EHDS) and connecting to EHDS services for use in medicines regulation; notes furthermore that the Scaled Agile Framework implementation involved transitioning the Agency's IT portfolio to the Agile way of working, establishing value streams aligned with its core mission, and operationalising product teams within them; calls on the Agency to learn from those experiences and to make use of the best practices derived from them in the future;

7. Reiterates the key role of the Agency in protecting human and animal health by assessing and supervising medicines for human or veterinary use and protecting public health by raising awareness on key issues including antimicrobial resistance and prevention of communicable diseases through vaccination;

8. Notes however that inadequate resources for the Agency may undermine the ability of the Agency to deliver on its mission and calls on the Commission and the Council to allocate adequate Union funding to ensure the Agency has enough resources to carry out all of its activities on the wide range of regulatory mechanisms, including facilitating the development of and access to medicines, supporting research and innovation and its responsibilities for monitoring and mitigating potential or actual shortages of critical medicines without any delay;

9. Acknowledges that 2022 was still characterised by a significant level of COVID-19 related activities, with a shift from pre- and initial marketing authorisation activities to post-authorisation activities;

10. Welcomes the fact that 52 % of applicants who have been granted a positive opinion for their medicinal product have received scientific advice or protocol assistance from the Agency during the development phase of their product, with this figure rising to 78 % for applicants for medicinal products with new active substances; is of the opinion that early advice has the potential to significantly streamline the approval process and lead to the development of safe and effective medicinal products;

([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).

([3]) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

([4]) Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).

Efficiency and gains

11. Is aware that during 2022 the Agency continued the implementation of its strategy to achieve efficiency gains, focusing on process improvement and digitalisation;

12. Notes that, through the work of its Digital Innovation Lab (DigiLab), the Agency explored opportunities to realise automations of administrative work; observes that DigiLab initiated 14 automation projects, prioritised and endorsed by the Digital Acceleration Leadership Team, alongside the Analytics Center of Excellence (ACE), including automations for email categorisation, clinical breakpoints list generation, and a pilot EU Reference Dates List Database for efficiency gains in maintenance and publication on the Agency's website; observes that the DigiLab also worked with ACE to pilot five potential solutions to business challenges;

13. Welcomes the fact that, as part of its digitalisation efforts in 2022, the Agency completed the integration of good clinical practice and good pharmacovigilance practice inspections into its IT platform, IRIS, enhancing efficiency, transparency, and collaborative work in line with the Agency's digital transformation programme, which oversees inspections for human and veterinary medicines under the centralised procedure or referral process upon request from the Committees for Medicinal Products for Human Use or Veterinary Use; invites the institution to find more internal procedures that could be streamlined via digitalisation;

14. Notes that, as part of the process improvement dimensions, during 2022 the Agency worked on the Agile transformation, with the aim of providing increased transparency, a reduced administrative burden and clearer accountability, through a new governance model and way of working in Information Management/IT;

15. Points out that in 2022 the Agency gradually resumed on-site activities at its building while maintaining flexible working arrangements, allowing up to 60 % teleworking monthly; temporary rules for business travel prioritised virtual participation in conferences, meetings, and trainings, with physical attendance considered for added strategic value, and a decision was implemented to alternate virtual and physical settings for scientific committee meetings and working parties to manage on-site capacity and contribute to carbon footprint control, resulting in lower carbon dioxide emissions compared to pre-pandemic years despite the resumption of physical activities;

16. Recalls the importance of increasing the digitalisation of the Agency in terms of internal operation and management but also in order to speed up the digitalisation of 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; 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; insists on the need to step up action against cyberattacks or infiltration attempts particularly those originating from Russia or China;

17. Notes with satisfaction that the Agency cooperates with other agencies, in particular with the European Centre for Disease Prevention and Control and with the European Food Safety Authority, including on the European Vaccination Information Portal, for monitoring vaccine safety and reporting side effects, as well as on antimicrobial consumption and resistance;

18. Invites the Agency to continue promoting cooperation with other Union agencies and international organisations, and fostering dialogue with stakeholders and citizens;

Staff policy

19. Notes that, on 31 December 2022, the establishment plan was 99,39 % implemented, with 658 temporary agents appointed out of 662 temporary agents authorised under the Union budget (compared to 657 authorised posts in 2021); notes that, in addition, 192 contract agents, 25 seconded national experts and 114 interims worked for the Agency in 2022;

20. Regrets the lack of gender balance on the Agency's management board, where 36 out of 67 (54 %) are men, while for the overall staff, 568 out of 865 (66 %) are women; regrets furthermore that in senior management positions, 17 out of 27 (63 %) are men; is strongly of the opinion that the gender balance among the members of the Agency's senior and middle management and the administrative staff needs to be improved with a faster pace;

21. Raises concerns about the geographical balance among the Agency's senior and middle management having only one managerial member of staff from Central-Eastern Europe; insists that improvements have to be made; asks the Agency to report back on this to the discharge authority;

22. Recalls the importance of ensuring gender balance and acknowledges in this regard that the Agency is implementing various initiatives in addressing the gender gap in senior management positions, including a management development programme, internal mobility opportunities, and the creation of management communities to encourage and support female staff; notes that a pipeline is being built from the Heads of Office/Service/Work stream, with a progressive increase in female managers; notes furthermore that the retirement of key senior male managers provides recruitment opportunities for females, complemented by an enhanced employer branding strategy, targeted recruitment marketing, the establishment of a Diversity and Inclusion Working Group and the endorsement of the diversity and inclusion charter in March 2022;

23. Notes that in 2022 the overtime declared of 72 463 hours was 30 % lower compared to 102 912 hours reported in 2021; notes furthermore that the average overtime in 2022 was 4,3 % compared to the 6,3 % reported in 2021, which is close to the average of 4,0 % recorded during the period 2016-2019; highlights the importance of a good work-life balance, flexible working hours, teleworking, and the right to disconnect, in relation to improving the wellbeing of the staff;

24. Welcomes the fact that in 2022 the Agency conducted a comprehensive well-being survey, and the resulting recommendations have been integrated into the Agency human resources strategy for 2023-2025;

25. Notes that the Agency has a policy on protecting the dignity of the person and preventing psychological and sexual harassment, and that the Agency is part of the interagency task force of confidential counsellors; looks forward to receiving their report and recommendations; notes that there were no reported cases of harassment in 2022 and encourages the Agency to continue and develop the work to prevent cases in the future as well;

Prevention and management of conflicts of interest and transparency

26. Observes that, to maintain impartiality and objectivity in the Agency's operations, it regularly adjusts the policies' scope and implementing processes vis-à-vis emerging risks stemming from new activities and/or interactions with new categories of stakeholders; notes that in 2022, as a result of the Agency's new responsibilities in the area of medical devices, *in vitro* medical devices, as well as the responsibilities under its extended mandate, the policy on competing interests for members of the Management Board, policy on competing interests for experts, and the implementing rules on handling declared interests of staff and candidates before recruitment, have been revised;

27. Notes that the Agency has a breach of trust (BoT) procedure, which sets out how it deals with incorrect or incomplete e-DoIs by experts and committee members, as well with disclosure of confidential information; observes that the BoT procedure was revised in December 2022; highlights the fact that the revised BoT procedure states that it also applies to the other bodies that have been established within the Agency under the extended mandate (e.g. ETF and both Shortages Steering Groups);

28. Observes that in 2022 two BoT procedures were initiated for experts; notes that one case involved a committee member failing to disclose a lecture honorarium, resulting in revised declarations and a three-year restriction and the second case concerned a committee member omitting a close family member interest, leading to a 9-month restriction from the Agency's activities;

29. Highlights that departing Agency staff sought permission for post-employment occupations, with 22 applications in 2022 resulting in varied authorisations, including both unrestricted and restricted cases; acknowledges that the Agency has been publishing decisions on senior members of staff that leave the organisation on its corporate website since December 2020, contributing significantly to transparency in handling competing interests;

30. Notes with satisfaction that the Commission's Internal Audit Service report, which was published during 2022 and focused on human resource matters, confirmed the robustness of the system in place based on a very high staff awareness of the risks involved and the maturity of the internal controls to manage potential conflicts of interest;

31. Notes that, as a technical, scientific body of the Union, the Agency does not formally engage or meet with lobbyists, however, the Agency does engage and meet with stakeholders in accordance with its formal stakeholder frameworks; notes furthermore that meetings with external stakeholders are public and the details are published on the events page of Agency's website;

32. Acknowledges the visibility that the Agency has achieved; is of the opinion that there is still room for it to achieve greater visibility in the media, internet, and social media in order to make its work and the dangers to our environment known to the citizens;

33. Notes that in 2022 the Agency received 676 requests for access to documents, fewer than the number of requests received in 2019 (783 requests) or 2021 (710 requests) and released 216 666 pages, more than compared to 165 943 in 2021 but considerably fewer than the 318 013 pages in 2019; notes that the Agency applies a queuing mechanism to manage the processing of multiple access to documents requests from the same requester representing a bottleneck for timely access to documents held by the Agency and discouraging requesters from introducing new requests; calls on the Agency to provide detailed information on the number of access to documents requests remaining inactivated in the queuing system and the average time spent in the queuing system before being activated; calls for the launch of an audit on the Agency's rules to process access to documents requests, the queuing mechanism, the evolution of requests over time and the effects on applicants;

34. Calls on the Commission to ensure that the Agency receives adequate resources to implement the tasks that were assigned to the Agency by the adoption of Regulation (EU) No 536/2014 and avoid staff shortages that will negatively affect the Agency's transparency policy, including with regard to timely publication of clinical data, meeting minutes and timely responses to access to documents requests;

Internal control

35. Observes that a questionnaire was prepared to assess the implementation, functioning, and improvement of the 17 principles within the internal control framework; notes that managers and staff responsible for specific principles or elements received the questionnaire, and interviews were conducted for further clarification; notes furthermore that the overall conclusion is that the internal control system is deemed to be effective and efficient, its components and principles are generally present and functioning reasonably well, while some principles could benefit from minor clarifications or additional information, and adjustments and improvements are suggested;

36. Draws attention to the fact that, as result of its relocation in 2019, the Agency leased a building in Amsterdam, which was fully fitted and furnished using the Dutch government's EUR 15 million incentive scheme, including the donation of furniture and catering equipment; notes that the Court found that the Agency had not assigned clear identification (such as labels with bar codes) to some of those assets, mainly furniture; notes furthermore that four inventory counts the Agency had carried out since relocation repeatedly showed discrepancies (which, with time, decreased from EUR 534 331 to EUR 15 000) between the list of assets donated by the Dutch government, the Agency's asset register and the assets found on the premises; highlights the fact that the absence of a complete and updated inventory list, specifying the location of tangible assets, is contrary to Article 87 of the Financial Regulation, and adversely affects the Agency's ability to ensure its assets are safeguarded; welcomes the fact that, with a view to continuously improving its processes, the Agency will release updated internal guidance for the management of its assets inventory, adopt a risk-based approach to the labelling of furniture and release a rolling physical checks plan to continuously confirm the accuracy of its inventory;

37. Notes the observation from the Court's report regarding the Agency's contribution towards certain types of staff childcare costs, such as pre- and after-school care in the Netherlands; notes that for school meals, the Court found that the Agency was not able to provide full evidence of the checks done to ensure that the costs of school meals were excluded, therefore putting into question whether such checks were systematically carried out; observes from the Agency's reply that meal costs are excluded from school fees and the Agency will file the evidence that school meal costs are excluded from the calculation of the contribution;

38. Notes the result of the activities carried out by the Agency's internal audit capability, with 6 critical and 19 very important recommendations issued in 2022; calls on the Agency to address the 14 major recommendations awaiting an improvement action plan as of 31 December 2022 and report back to the discharge authority on the developments in this regard;

Other comments

39. Welcomes the fact that the Agency aligned its long-term climate objectives with the target laid down in Regulation (EU) 2021/1119 of the European Parliament and of the Council ([5]) of a 55 % net reduction of greenhouse gas emissions by 2030 (compared to 1990 levels) and achieving climate neutrality by 2050; notes that for energy and water consumption, the Agency translated those objectives into a 15 % reduction per square metre of office space to be achieved between 2012 and 2021; observes that this target took into account the Agency's growth in that period, and the fact that it had moved into a bigger but also more energy-efficient building, following its relocation from London to Amsterdam; notes that the target was exceeded both for energy and water achieving a 45 % reduction in energy consumption and 63 % in water use per square metre;

40. Notes that the Agency is preparing for the Eco-Management and Audit Scheme certification;

41. Welcomes the fact that in 2022, in order to increase cybersecurity, the Agency adopted the Information Security Strategy and the related implementation plan aiming to enhance the existing safeguards and security processes to protect the Agency's information assets whilst supporting new business and technological challenges; notes that other important measures were also implemented in 2022 including the establishment of the security training and awareness programme and the implementation of the Security Operation Centre, which aims to continuously monitor and improve the Agency's security posture while preventing, detecting, analysing, and responding to cybersecurity incidents; notes furthermore that the Agency has been working in close collaboration with the Computer Emergency Response Team for the EU institutions, bodies and agencies and the European Union Agency for Cybersecurity covering many aspects of the information security and cybersecurity domains, also including discussions and regular updates on the upcoming cybersecurity regulation for Union institutions, agencies, and bodies;

42. Commends the Agency for issuing initial advice for sponsors on how to manage the conduct of clinical trials in the context of the disruptions caused by the Russian invasion of Ukraine;

43. Refers, for other observations of a cross-cutting nature accompanying its decision on discharge, to its resolution of 11 April 2024 ([6]) on the performance, financial management and control of the agencies.

([5]) Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law') (OJ L 243, 9.7.2021, p. 1).

([6]) Texts adopted, P9_TA(2024)0280.