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A9-0106/2023

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REPORT

on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2021
(2022/2109(DEC))

Committee on Budgetary Control

Rapporteur: Katalin Cseh

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1. PROPOSAL FOR A EUROPEAN PARLIAMENT DECISION

on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2021
(2022/2109(DEC))

The European Parliament,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2021,

– having regard to the Court of Auditors' annual report on EU agencies for the financial year 2021, 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 2021, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of 28 February 2023 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2021 (06248/2023 – C9-0091/2023),

– 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 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,

[1] OJ C 412, 27.10.2022, p. 12.
[2] OJ C 412, 27.10.2022, p. 12.
[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.

– 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 (A9-0106/2023),

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 2021;

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).

2. PROPOSAL FOR A EUROPEAN PARLIAMENT DECISION

on the closure of the accounts of the European Medicines Agency for the financial year 2021
(2022/2109(DEC))

The European Parliament,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2021,

– having regard to the Court of Auditors' annual report on EU agencies for the financial year 2021, 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 2021, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of 28 February 2023 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2021 (06248/2023 – C9-0091/2023),

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

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[1] OJ C 412, 27.10.2022, p. 12.
[2] OJ C 412, 27.10.2022, p. 12.
[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.

– 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 (A9-0106/2023),

1. Approves the closure of the accounts of the European Medicines Agency for the financial year 2021;

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).

3. MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

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 2021
(2022/2109(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 2021,

– 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 (A9-0106/2023),

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 2021 was EUR 379 228 000, representing an increase of 2,56 % compared to 2020; whereas the Agency is a fee-funded agency, with approximately 89,40 % of its 2021 revenue stemming from fees paid by the pharmaceutical industry for services provided, 9,90 % stemming from the Union budget and 0,7 % stemming from external assigned revenue;

B. whereas the Court of Auditors (the 'Court') in its report on the annual accounts of the Agency for the financial year 2021 (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 that budget monitoring efforts during the financial year 2020 resulted in a budget implementation rate of current year commitment appropriations of 96,38 %, representing a decrease of 2,46 % compared to 2020; regrets that the current year payment appropriations execution rate was 72,36 %, representing a decrease of 6,11 % compared to 2020;

Performance

2. Notes that in 2021, despite the difficulties caused by the COVID 19-pandemic, the Agency continued to promote a functioning single market for human and veterinary medicines, by acting as the hub of the European network of regulatory medicines authorities that implements the applicable Union legislative framework for such products; commends the Agency for its support regarding the Union's response to the COVID 19-pandemic, by assessing in a timely manner vaccines and therapeutics for the

[1] OJ C 141, 29.3.2022, p. 26.

prevention and treatment of infections from SARS-CoV-2 virus;

3. Commends the Agency for its significant achievements in 2021 with, among others, four COVID-19 vaccines and five COVID-19 treatments recommended for approval, 92 new human medicines and 12 new veterinary medicines recommended for marketing authorisation, six PRIME-designated medicines recommended for approval and 19 orphan-status designations confirmed; further commends the Agency for the progress made towards a fully functional Clinical Trials Information System and for the launch of the Accelerating Clinical Trial in the EU initiative ;

4. Notes that in 2021 the targets of most of the Agency's workload and key performance indicators were achieved or exceeded, while the achievement of most of the objectives set was on track or completed; further notes, with regard to the follow-up to last year's discharge observations, that despite the difficulties caused by the COVID-19 pandemic, the Agency is progressing in introducing new performance management tools, concepts and processes through the development of a comprehensive Performance and Development Programme which entails the cascading of objectives from higher levels down to team or individual level and the regular monitoring of progress through continuous performance management; calls on the Agency to report to the discharge authority once the embedding of those initiatives in the Agency's operations is completed;

5. Notes, following the cyberattack in December 2020, that the Agency has further strengthened its cybersecurity capabilities and defence; welcomes in this context the creation of the Information Security Management Steering Committee in order to provide Agency-wide oversight and ownership of and direction to the information security strategy and its implementation plan, the establishment of a Security Operation Centre with round-the-clock monitoring of the Agency's network and the development of a security awareness and training programme which aims to foster a strong security culture within the Agency; calls on the Agency to report to the discharge authority on the results that those measures will bring; notes that the revision of the Agency's information security strategy is underway, with the aim of putting into place a three-year improvement road map in line with best practices of similar organisations;

6. Welcomes the Agency's efforts to combat antimicrobial resistance, in particular the adoption of the Committee for Veterinary Medicinal Products (CVMP) strategy on antimicrobials 2021-2025; notes with satisfaction the fact that the overall sales of veterinary antimicrobials in European countries were 47% lower in 2021 than in 2011 according to the European Surveillance of Veterinary Antimicrobial Consumption project report published in November 2022 entitled 'Sales of veterinary antimicrobial agents in 31 European countries in 2021 - Trends from 2010 to 2021';

7. Stresses that the replacement of animal testing shall be a priority in medicine development during the application of the 3Rs - replace, reduce and refine animal use for the development, manufacturing and testing of medicines– principles; regrets that in 2021 the 3Rs Working Party had to be put on hold due to the business continuity planning policy as a result of the COVID-19 pandemic, therefore the Agency did not prepare an activity report on this issue; welcomes the activity restart of the 3Rs Working Party in late 2022 and the organisation of meetings with stakeholders on this issue in 2023; expects that the Agency will produce its biennial reports on 3Rs actions

as soon as possible;

8. Notes the Agency’s formal working arrangements with its main Union agency partners (European Centre for Disease Prevention and Control, European Food Safety Authority, European Chemicals Agency and European Monitoring Centre for Drugs and Drug Addiction), laying out the nature of the collaboration and mutual consultation in areas of common interest; notes the Agency’s active cooperation with the European Health Emergency Preparedness and Response Authority on medical countermeasures and the preparation of a Memorandum of Understanding between them to clarify their roles and responsibilities and ensure complementarity; notes with satisfaction that the Agency regularly participates in joint procurement procedures with other Union decentralised agencies and with Commission services and organises joint procurement procedures which are open to other Union agencies;

Staff policy

9. Notes that, on 31 December 2021, the establishment plan was 98,02 % implemented, with 644 temporary agents appointed out of 657 temporary agents authorised under the Union budget (compared to 596 authorised posts in 2020); notes that, in addition, 206 contract agents, 28 seconded national experts and 138 interims worked for the Agency in 2021;

10. Expresses concern that the addition of new tasks and the increasing fee-related workload due to the growing portfolio of authorised medicines over the years was not accompanied by an adequate increase in the Agency's staff, which puts the Agency under significant pressure; invites the Agency to explore ways of surveying the staff regarding their well-being and deploying methods that would prevent burn-out and decreased performance;

11. Notes with concern the lack of gender balance within the Agency’s senior management, with 17 out of 28 (61 %) being men; notes the gender balance in the Agency’s management board, with 37 out of 66 (56%) being men and for overall staff with 562 out of 850 (66%) being women; calls on the Agency to take concrete measures to increase gender balance at all levels of the Agency’s hierarchy as soon as possible and report back to the discharge authority;

12. Acknowledges the ongoing work done by the Agency on establishing a long-term human resources policy framework with, at its core, work-life balance; welcomes in this context the full implementation of a hybrid working environment, the Agency’s wellbeing and employee assistance programmes, the creation of a working group for workload management, a dedicated health team within the human resources (HR) function, as well as training courses and surveys on wellbeing;

13. Notes that the considerable increase by 61 temporary agents decided on by the budgetary authority helped the Agency tackle the additional workload caused by the COVID-19 pandemic, as well as activities related to the implementation of the Agency’s extended mandate;

14. Highlights the importance of developing a long term HR policy on work-life balance, lifelong guidance and the offering of specific training possibilities for career development, gender balance at all staff levels, teleworking, the right to disconnect, the

enhancement of a geographical balance to have an appropriate representation from all Member States, and the recruitment and integration of people with disabilities as well as ensuring that they are treated equally and that their opportunities are widely promoted;

Procurement

15. Notes with concern that 2021 was the third year in a row when the Court raised new procurement-related observations for the Agency; notes from the Court's report the observation regarding the Agency's overestimation of the value of a framework contract, whereby a lower threshold regarding the financial and economic capacity requirement (annual turnover) would have allowed more companies to submit tenders; calls on the Agency to review the shortcomings of its procurement processes and also follow the Court's recommendations;

16. Notes 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, based on the Court's reports of 2020 and 2021, that the estimated amount corresponding to such liabilities has risen from EUR 377 million on 31 December 2020 to EUR 383 million on 31 December 2021; notes that the Agency reached an agreement with the owner of the building to sublet its former premises from July 2019; notes that the terms of the sublease are consistent with the head lease and it lasts until 2039; acknowledges that subletting the Agency's premises in a third country means diverting resources to perform an activity outside of the Agency's legal mandate; further acknowledges the need for a political decision in order to secure a long-term resolution on this issue;

17. Notes the measures taken by the Agency to address the Court's observation from 2019 regarding a framework contract signed by the Agency with three companies for the supply of temporary workers; further notes, as a result, that the status of this observation has been upgraded by the Court from 'outstanding' to 'ongoing'; observes that the Court agreed to reassess this observation for 'closing', following the launch of the new procedure for supply of temporary agency workers on 25 May 2022;

18. Recalls the importance for all procurement procedures, to ensure fair competition between tenderers and to procure goods and services at the best price, respecting the principles of transparency, proportionality, equal treatment and non-discrimination; asks for the implementation of the e-procurement IT tools developed by the Commission; calls for an updated clarification of the procedures and templates in the procurement guidelines; notes with concern the Court's observation that public procurement weaknesses are increasing and remain the largest source of irregular payments for most of the agencies;

Prevention and management of conflicts of interest, and transparency

19. 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 2021 no internal whistleblowing case was reported, however, 29 reports of external whistleblowing cases were received, of which 23 cases were closed and 6 cases are still ongoing; calls on the Agency to report to the discharge authority on the progress made in the ongoing cases;

20. Notes that the Agency published the CVs and declarations of interests of its

management board members, its senior management and the scientific experts involved in the Agency's work; further notes that in 2021 no case of conflicts of interest was reported by the Agency; commends the Agency for having put in place rules for the members of its board on conflicts of interest and 'revolving door' situations;

21. Welcomes the further steps taken in order to enhance the transparency of the Agency's activities by, among others, reporting the meetings that the Agency's staff has with external stakeholders, and the availability of such reporting on the website of the Agency;

22. Insists on the need to maintain systematic rules on transparency, incompatibilities, conflict of interests, illegal lobbying and revolving doors; calls on the Agency to revise and improve its code of conduct and continue strengthening its internal control and audit mechanisms, including the setting up of an internal anti-corruption mechanism;

23. Stresses that despite the majority of funding coming from private sources, the Agency is a public authority; underlines that public trust and guarantees of the Agency's independence and integrity are crucial and therefore a high degree of transparency needs to be ensured through all its activities to avoid regulatory capture and ensure citizens maintain their faith in the pharmaceutical legal and regulatory framework in the Union;

Internal control

24. Notes that the internal control system which the Agency has in place, both in terms of the individual elements, and the system as a whole, is effective overall, with some improvements needed to further enhance the effectiveness of some specific elements; notes, furthermore, that in 2021 the Agency's executive board approved a new approach and new internal guidance on the methodology for financial ex-post controls, introducing new timelines for carrying out the exercise in a rolling, 18-month period; notes that the internal control procedures highlighted no significant weaknesses, although two areas of controls were identified for potential improvements and are currently being addressed by specific improvement action plans; calls on the Agency to report to the discharge authority on the developments in this regard;

25. Notes with concern the observation from the Court's report regarding multiple procedural deficiencies in two audited recruitment procedures, which undermine the principles of transparency and equal treatment; calls on the Agency to address the weaknesses found by the Court in the area of recruitment and strengthen its internal control system; calls on the Agency to report to the discharge authority on the progress made in this regard;

26. Deplores the fact that procedural deficiencies in recruitment procedures undermine the principles of transparency and equal treatment; requests that the Agency improve its internal recruitment procedure to clarify evaluation processes and vacancy notices; points out that in the Agency's annual report the number of heads of department in the year 2021 was 18, while the number of heads of departments was 13 in 2020.

27. Recalls the importance to strengthen Management and control systems to ensure the proper functioning of the Agency; strongly insists on the requirement of an effective Management and control systems to avoid potential cases of conflict of interest, missing ex-ante/ex-post controls, inadequate management of budgetary and legal commitments,

and failures to report issues in the register of exceptions;

Digitalisation & green transition

28. Notes that in 2021 the Agency pursued its efficiency gains strategy, building on the Digital Transformation, building on the activities carried out by the Digital Business Transformation task force; notes with appreciation that the activities included the exploration of artificial intelligence, machine learning and robotics to build pragmatic solutions to existing business needs of the Agency, and the acceleration of innovation via the Digital Innovation Lab , which developed a framework to analyse the processes with a view to enhancing efficiency through technology and digital innovation across the Agency;

29. Notes with appreciation the progress made regarding the administration digitalisation programme of the Agency aimed at modernising processes and tools used in staff management, finance and planning areas; commends the rollout of phase 1 and 2 of the Performance and Development programme in 2021, that consists of, among other things, the launch of a new digital tool to manage all performance and development processes which is integrated with the existing onboarding systems, and the implementation of the digital personal file for all statutory staff, replacing the historical paper personal file and scanned working files;

30. Welcomes the efforts made by the Agency in 2021 for increased sustainability to reduce the carbon footprint from its activities; notes that such efforts led to various positive outcomes, including a significant reduction in the Agency's energy and water consumption; welcomes the Agency's progress in 2021 regarding its registration in the Eco-management and Audit Scheme , the update to the Agency's Environmental Management (EM) system to identify the resources that will help to embed EM activities in its operational business processes and to monitor the Agency's environmental footprint by applying the Greenhouse Gas Protocol;

31. 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; invites the Agency to switch to paper-less document management and processes where possible; 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;

32. Encourages the Agency to work in close cooperation with ENISA European Union Agency for Cybersecurity and CERT-EU Computer Emergency Response Team for the EU Institutions, bodies and agencies and to carry out regular risk assessments of its IT infrastructure and to ensure regular audits and tests are carried out on its cyber defences; suggests to offer regularly updated cybersecurity-related training programmes to all staff members within the Agency; calls on the Agency to develop its cybersecurity policy swifter, deliver it before the 31st of December 2023 and report back to the discharge authority;

Business continuity along crisis

33. Notes that, as a result of putting in place business continuity planning throughout 2021,

some of the Agency's activities had to be put on hold, delayed or scaled back; further notes that the Agency continued to monitor its business continuity plan and public health threat plan, in order to protect staff, delegates and contractors' health and safety while continuing to deliver on its mandate;

34. Notes that the Agency took a number of measures to monitor and mitigate the effects of the COVID 19-pandemic, such as managing health and safety risks by implementing social distancing and allowing employees to work from home; notes that the Agency's operations and results were not significantly impacted by the COVID 19-pandemic;

Other comments

35. Commends the Agency for its efforts in 2021 to provide clear, transparent, accurate and timely information on the approval and supervision of COVID-19 vaccines and treatments in the Union with unprecedented speed and frequency; acknowledges that the Agency's communication was key to reassuring the Union's citizens, fighting mis- and disinformation, building trust and protecting public health; commends the Agency's improved metrics and positive feedback regarding its website traffic, press conferences and social media accounts in 2021;

36. Notes that in 2021 the Agency developed a new five-year framework strategy for external communication and engagement, covering 2021 to 2025, that aims to build a better understanding of the Agency and its work among Union citizens, as well as to provide a strategic framework for the development of annual communication and engagement plans; notes that the new framework strategy lays out goals such as an increase of public health impact, strengthened collaboration with partners and stakeholders and establishment of optimised crisis-communication processes amongst others;

37. Calls on the Agency to continue to develop its synergies with other Union agencies, for instance in relation to HR, building management, IT services and security, and to reinforce its cooperation, its exchange of good practices and its discussions regarding areas of mutual interest with those agencies, with a view to improving efficiency;

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38. Refers, for other observations of a cross-cutting nature accompanying its decision on discharge, to its resolution of [...] 2023[2] on the performance, financial management and control of the agencies.

[2] Texts adopted, P9_TA(2023)0000.

13.2.2023

OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND FOOD SAFETY

for the Committee on Budgetary Control

on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2021
(2002/2109(DEC))

Rapporteur for opinion: Pascal Canfin

SUGGESTIONS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on Budgetary Control, as the committee responsible, to incorporate the following suggestions into its motion for a resolution:

1. Reiterates the key role of the European Medicines Agency ('the EMA') in protecting and promoting public human and animal health by assessing and supervising medicines for human or veterinary use;

2. Notes that the EMA's authorised appropriations in the initial budget totalled EUR 385,919,000, representing a 7.78% increase over the 2020 initial budget, nevertheless, the final 2021 budget of the EMA mounted to EUR 379,288,000;

3. Recalls that the EMA is a fee-funded agency, with 89,37 % of its 2021 revenue stemming from fees paid by the pharmaceutical industry, 9,92 % stemming from the Union budget and 0,7 % from various other sources;

4. Stresses that despite the majority of funding coming from private sources, the EMA is a public authority; underlines that public trust and guarantee of the Agency’s independence and integrity is crucial and therefore a high degree of transparency needs to be ensured through all its activities to avoid regulatory capture and ensure citizens maintain their faith in the pharmaceutical legal and regulatory framework in the EU;

5. Notes that 644 of the 657 authorised posts were occupied on 31 December 2021, compared to the 596 posts out of 596 in 2020;

6. Reiterates that transparency and the timely release of information about medicines is key to reinforcing public trust in regulatory decisions and the medicines placed onto the EU market; acknowledges that in 2021, the EMA continued to focus on the assessment of vaccines and therapeutics for COVID-19 and on the evaluation of the quality, safety, and efficacy of these products as part of the EU response to the global pandemic; welcomes the continued efforts of the EMA to maintain a high level on transparency in

relation to medicines against COVID-19;

7. Notes with regret that the publication of clinical data and clinical study reports, initiated in 2016, was put on hold at the end of 2018 due to the relocation from London to Amsterdam and subsequently due to the Covid-19 pandemic; calls on the Agency to take up the publication of clinical data without delay; calls on the Agency to stick to the transparency rules and obligations laid down in the Clinical Trials Regulation adopted in 2014 as well as in the Regulation 1049/2001;

8. Welcomes the proposal to extend the EMA's mandate, which has entered negotiations in 2021, but expresses concern that the addition of significant new tasks and its increasing workload over the years has not been accompanied by sufficient corresponding increases in the EMA's staff and resources, and that such a shortage of staff puts the continuity of its operations under significant pressure and threatens the quality of the agency's work; similarly, notes with concern the lack of remuneration for national experts in some of the Agency's activities which may lead to delays and lower quality of scientific assessments;

9. Notes with concern that the EMA has not received any additional resources to recruit new staff to implement the new tasks that were assigned to the Agency by adoption of the Clinical Trials Regulation, in particular for the development of the Clinical Trials database and portal; notes with concern that staff shortages negatively affect the Agency's transparency policy, including in regards of timely publication of clinical data, meeting minutes and timely responses to the access to documents requests; regrets that in order to comply with its new obligations, EMA compensated the staff shortages, including IT staff, with interim staff which are typically more expensive, are subject to high levels of turnover and hence require more time to be adequately trained;

10. Highlights the fact that, in 2021, the EMA recommended 92 human medicines and 12 veterinary medicines for marketing authorisation; 54 of those human medicines and 7 of those veterinary medicines had a new active substance that had never been authorised in the Union before;

11. Welcomes that EMA recommended for approval in 2021 4 more vaccines and 5 new treatments to combat COVID-19 pandemic;

12. Notes with satisfaction that the EMA 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;

13. Notes that after the cyberattack that EMA suffered in December 2020 the agency has conducted a revision of EMA's information security strategy; in this context welcomes that EMA has followed the recommendation of the Court of Auditors[1] asking EU institutions, bodies and agencies to have an IT security risk management framework covering the entirety of their IT infrastructure and carry out regular risk assessments,

[1] Special Report No 05/2022 'Cybersecurity of EU institutions, bodies and agencies: Level of preparedness overall not commensurate with the threats', p. 44

and to provide systematic awareness training for all staff, including management;

14. Welcomes the Court of Auditors acknowledgment of the EMA as one of the nine agencies that had introduced their own internal rules to deal with the governing of the activities of members of agencies' boards[2] ; calls on the Agency to ensure that all management board members, members of EMA advisory bodies and stakeholder groups and their alternates have dutifully submitted the required declarations of interest that a high level of compliance with conflict of interest rules is maintained;

15. Welcomes EMA's efforts to combat antimicrobial resistance, in particular the adoption of the 2021-2025 EMA Committee for Veterinary Medicinal Products' Strategy on Antimicrobials; notes with satisfaction the fact that the overall sales of veterinary antimicrobials in European countries were 47% lower in 2021 than in 2011 according to the EMA annual European Surveillance of Veterinary Antimicrobial Consumption report 2021.

16. Notes with concern the Court of Auditors' observation about the fact that since the 2019 financial year, it has raised new procurement-related observations every year for the EMA[3]; notes that three of the four procurement-related observations raised between 2019 and 2021 are for a matter of interpretation of the rules and were not deemed irregular.

17. Notes with satisfaction that the EMA has properly addressed the two observations made by the Court of Auditors in its 2020 annual report regarding the appointment of selection panels in recruitment procedures and the catering and restaurant services framework contract[4] ; recalls a finding by the Court of Auditors in its annual report 2021, of remaining shortcomings related to transparency in recruitment procedures; notes the effort of EMA to improve its internal hiring guidelines;

18. Expresses concern that the addition of new tasks and increasing fee-related workload due to the growing portfolio of authorised medicines over the years was not accompanied by an adequate increase in the EMA's staff, which puts the Agency under significant pressure;

19. Welcomes the fact that the Court of Auditors has stated that it has obtained reasonable assurances that the EMA's annual accounts for 2021 are reliable and that the underlying transactions are legal and regular;

20. Recommends, based on the facts available, that discharge be granted to the Executive Director of the European Medicines Agency in respect of the implementation of the EMA's budget for the financial year 2021.

[2] 2021 Audit of EU agencies in brief: Introducing the European Court of Auditors' 2021 annual report on EU agencies, p. 40
[3] Annual Report on EU agencies for the financial year 2021, p. 43
[4] Annual Report on EU agencies for the financial year 2021, p. 181

INFORMATION ON ADOPTION IN COMMITTEE ASKED FOR OPINION

Date adopted	9.2.2023
Result of final vote	+: 67 –: 7 0: 1
Members present for the final vote	Mathilde Androuët, Traian Băsescu, Aurélia Beigneux, Hildegard Bentele, Alexander Bernhuber, Michael Bloss, Delara Burkhardt, Pascal Canfin, Mohammed Chahim, Tudor Ciuhodaru, Nathalie Colin-Oesterlé, Bas Eickhout, Cyrus Engerer, Agnès Evren, Heléne Fritzon, Malte Gallée, Andreas Glück, Catherine Griset, Teuvo Hakkarainen, Anja Hazekamp, Martin Hojsík, Pär Holmgren, Jan Huitema, Petros Kokkalis, Ewa Kopacz, Joanna Kopcińska, Peter Liese, César Luena, Marian-Jean Marinescu, Sara Matthieu, Liudas Mažylis, Tilly Metz, Silvia Modig, Dolors Montserrat, Ljudmila Novak, Jutta Paulus, Stanislav Polčák, Erik Poulsen, Manuela Ripa, María Soraya Rodríguez Ramos, Sándor Rónai, Christine Schneider, Ivan Vilibor Sinčić, Maria Spyraki, Véronique Trillet-Lenoir, Achille Variati, Petar Vitanov, Alexandr Vondra, Pernille Weiss, Sarah Wiener, Emma Wiesner, Michal Wiezik, Tiemo Wölken, Anna Zalewska
Substitutes present for the final vote	João Albuquerque, Eric Andrieu, Nicolás González Casares, Robert Hajšel, Billy Kelleher, Ska Keller, Sirpa Pietikäinen, Robert Roos, Massimiliano Salini, Christel Schaldemose, Jadwiga Wiśniewska
Substitutes under Rule 209(7) present for the final vote	Karolin Braunsberger-Reinhold, Clare Daly, Ilan De Basso, Jarosław Duda, Jens Geier, Niclas Herbst, Beata Kempa, Karsten Lucke, Johan Nissinen, Jörgen Warborn

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

67	+
ECR	Beata Kempa, Joanna Kopcińska, Alexandr Vondra, Jadwiga Wiśniewska, Anna Zalewska
PPE	Traian Băsescu, Hildegard Bentele, Alexander Bernhuber, Karolin Braunsberger-Reinhold, Nathalie Colin-Oesterlé, Jarosław Duda, Agnès Evren, Ewa Kopacz, Peter Liese, Marian-Jean Marinescu, Liudas Mažylis, Dolors Montserrat, Ljudmila Novak, Sirpa Pietikäinen, Stanislav Polčák, Massimiliano Salini, Christine Schneider, Maria Spyraki, Jörgen Warborn, Pernille Weiss
Renew	Pascal Canfin, Andreas Glück, Martin Hojsík, Jan Huitema, Billy Kelleher, Erik Poulsen, María Soraya Rodríguez Ramos, Véronique Trillet-Lenoir, Emma Wiesner, Michal Wiezik
S&D	João Albuquerque, Eric Andrieu, Delara Burkhardt, Mohammed Chahim, Tudor Ciuhodaru, Ilan De Basso, Cyrus Engerer, Heléne Fritzon, Jens Geier, Nicolás González Casares, Robert Hajšel, Karsten Lucke, César Luena, Sándor Rónai, Christel Schaldemose, Achille Variati, Petar Vitanov, Tiemo Wölken
The Left	Clare Daly, Anja Hazekamp, Petros Kokkalis, Silvia Modig
Verts/ALE	Michael Bloss, Bas Eickhout, Malte Gallée, Pär Holmgren, Ska Keller, Sara Matthieu, Tilly Metz, Jutta Paulus, Manuela Ripa, Sarah Wiener

7	-
ECR	Johan Nissinen, Robert Roos
ID	Mathilde Androuët, Aurélia Beigneux, Catherine Griset, Teuvo Hakkarainen
NI	Ivan Vilibor Sinčić

1	0
PPE	Niclas Herbst

Key to symbols:
+ : in favour
- : against
0 : abstention

INFORMATION ON ADOPTION IN COMMITTEE RESPONSIBLE

Date adopted	22.3.2023
Result of final vote	+: 22 –: 1 0: 0
Members present for the final vote	Gilles Boyer, Olivier Chastel, Caterina Chinnici, Ilana Cicurel, Corina Crețu, José Manuel Fernandes, Luke Ming Flanagan, Daniel Freund, Isabel García Muñoz, Monika Hohlmeier, Jean-François Jalkh, Claudiu Manda, Alin Mituța, Markus Pieper, Petri Sarvamaa, Eleni Stavrou, Angelika Winzig, Lara Wolters, Tomáš Zdechovský
Substitutes present for the final vote	Maria Grapini, Niclas Herbst, Mikuláš Peksa
Substitutes under Rule 209(7) present for the final vote	Anne-Sophie Pelletier

FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

22	+
PPE	José Manuel Fernandes, Niclas Herbst, Monika Hohlmeier, Markus Pieper, Petri Sarvamaa, Eleni Stavrou, Angelika Winzig, Tomáš Zdechovský
Renew	Gilles Boyer, Olivier Chastel, Ilana Cicurel, Alin Mituța
S&D	Caterina Chinnici, Corina Crețu, Isabel García Muñoz, Maria Grapini, Claudiu Manda, Lara Wolters
The Left	Luke Ming Flanagan, Anne-Sophie Pelletier
Verts/ALE	Daniel Freund, Mikuláš Peksa

1	-
ID	Jean-François Jalkh

0	0

Key to symbols:
+ : in favour
- : against
0 : abstention