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# REPORT

on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2020
(2021/2132(DEC))

Committee on Budgetary Control

Rapporteur: Tomáš Zdechovský

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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 2020**
**(2021/2132(DEC))**

*The European Parliament*,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2020,

– having regard to the Court of Auditors' annual report on EU agencies for the financial year 2020, 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 2020, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of 28 February 2022 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2020 (06003/2022 – C9-0087/2022),

– 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,

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[1] OJ C 439, 29.10.2021, p. 3. ECA annual report on EU agencies for the 2020 financial year: https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=59697.
[2] OJ C 439, 29.10.2021, p. 3. ECA annual report on EU agencies for the 2020 financial year: https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=59697.
[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 (A9-0103/2022),

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 2020;

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 2020**
**(2021/2132(DEC))**

*The European Parliament*,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2020,

– having regard to the Court of Auditors' annual report on EU agencies for the financial year 2020, 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 2020, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of 28 February 2022 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2020 (06003/2022 – C9-0087/2022),

– 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,

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[1] OJ C 439, 29.10.2021, p. 3. ECA annual report on EU agencies for the 2020 financial year: https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=59697.
[2] OJ C 439, 29.10.2021, p. 3. ECA annual report on EU agencies for the 2020 financial year: https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=59697.
[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 (A9-0103/2022),

1. Approves the closure of the accounts of the European Medicines Agency for the financial year 2020;

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 2020**
**(2021/2132(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 2020,

– 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 (A9-0103/2022),

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 2020 was EUR 369 749 000, representing an increase of 6,63 % compared to 2019; whereas the inflation rate in the Union was 0,7% in 2020; whereas the Agency is a fee-funded agency, with approximately 84,00 % of its 2020 revenue stemming from fees paid by the pharmaceutical industry for services provided, 15,92 % stemming from the Union budget and 0,08 % 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 2020 (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 2020 resulted in a budget implementation rate of 98,83 %, representing an increase of 0,27 % compared to 2019; notes that the payment appropriations execution rate was 78,47 %, representing a decrease of 4,58 % compared to 2019;

2. Notes the Agency's decision to waive all fees for scientific advice applications from developers of potential COVID-19 therapeutics or vaccines, as of 13 March 2020, and welcomes the waiving of all fees for provision of scientific advice to academic researchers developing orphan medicines from 19 June 2020; believes that other instances of waiving fees subject to specific criteria set out by the Agency, in particular regarding small and medium-sized enterprises (SMEs), should follow;

***Performance***

[1] OJ C 114, 31.3.2021, p.25.

3. Emphasises the important role of the Agency in protecting and promoting public and animal health by making independent, science-based recommendations on the quality, safety and efficacy of medicines, and providing scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;

4. Recognises the contribution made by the Agency in giving six medicines a recommendation for marketing authorisation following an accelerated assessment, thirteen medicines a recommendation for conditional marketing authorisation, and authorising five medicines under exceptional circumstances;

5. Notes that, despite the unprecedented difficulties since the start of the global COVID-19 pandemic in 2020, the Agency continued to act in the interests of the public health of all European citizens as they were confronted with COVID-19, by acting as the hub of the European network of regulatory medicines authorities that implements the applicable Union legislative framework for such products; highlights the important role the Agency played in preparation of the Union's response to the COVID-19 pandemic and praises its efforts to effectively analyse and to quickly approve vaccines against COVID-19 in the Member States;

6. Is pleased that the Agency successfully maintained the quality and continuity of its operations whilst relocating its seat to its new premises in Amsterdam following the United Kingdom's withdrawal from the Union; notes that potential liabilities arising from the lease on the Agency's former office premises in London remain a matter of concern; recognises that the Agency was able to respond effectively to the workload associated with the COVID-19 pandemic and welcomes the Agency's work on facilitating access to new vaccines and therapeutics to treat and prevent the spread of COVID-19;

7. Highlights the fact that, in 2020, the Agency recommended 97 new human medicines for marketing authorisation, including 39 new active substances, and 20 new veterinary medicines, including 13 new active substances;

8. Emphasises the fact that, despite the Agency's hard work in 2020, the COVID-19 pandemic challenged the existing public health security infrastructure, and underlines the need to strengthen the capabilities of the Agency so as to improve its resilience and effectiveness during periods of emergency; stresses that the European Green Deal also requires additional efforts from the Agency, which justify an expansion of resources; welcomes the fact that steps have been taken to redesign the public health security infrastructure in the Union, including via the EU4Health Programme established by Regulation (EU) 2021/522[2], , via Regulation (EU) 2022/123[3] and via the communication of the Commission of 25 November 2020 entitled 'Pharmaceutical Strategy for Europe'; calls upon the Court to expand in its audit for the 2021 financial year on the functioning of the Agency within the adjusted institutional context; calls upon the Court to expand on whether within the adjusted institutional setting, the

[2] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme')for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1).
[3] 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).

Agency has enough resources to implement its expanded mandate effectively;

9. Notes, with regard to the follow-up to last year's discharge observations, that the Agency is revising its set of indicators and metrics with the objective of further reducing complexity, increasing transparency and extending the efficacy of monitoring its activities; calls on the Agency to report to the discharge authority on the developments in this regard;

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

11. Highlights the importance of involving the relevant stakeholders, such as representatives of health professionals, of patients and of other parties, in the light of the alarming prevalence of disinformation regarding the COVID-19 pandemic in public debate on protection of public health, and calls on the Agency to continue to contribute to such debate as actively as possible, based on the latest scientific knowledge;

12. Welcomes the fact that tackling increasing antimicrobial resistance, in particular by supporting the development of new medicines, collecting data on veterinary antimicrobial consumption and promoting responsible use of antimicrobial medicines, remains one of the Agency's priorities, even in the light of the current situation;

13. Emphasises that the COVID-19 pandemic is impacting all aspects of health care, including the availability of medicines, due to supply chain disruptions; considers that the situation has only served to highlight the need, of which we were already aware, for the Union to reach the highest possible level of self-sufficiency in the development and production of medicines; welcomes the Agency's commitment to continue contributing to the development and strengthening of the Union's response system in the event of reduced availability of medicines;

14. Welcomes the level of assistance that the Agency has provided to companies developing vaccines and medicines against COVID-19; lauds its consistently scientific approach, which places the health of Union citizens above all else;

15. Notes, regarding the follow-up to last year's discharge observations, that the Agency shares services with the Commission and other Union agencies and often participates in joint inter-agency procurements; further notes that the Agency cooperates with the EU Agencies Network in order to share and adopt best practices aimed at increasing efficiency among all agencies and joint undertakings; notes that, as a result of a cyberattack in December 2020, the Agency increased its cooperation in the area of cybersecurity, in particular with the Computer Emergency Response Team for the EU institutions, bodies and agencies (CERT-EU) and the European Union Agency for Law Enforcement Cooperation (Europol), as well as an external third-party service provider with specific expertise in IT security-incident response;

16. Notes that, according to the Court's Special Report No 22/2021 '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;

***Staff policy***

17. Welcomes the fact that, on 31 December 2020, the establishment plan was 100,00 % implemented, with 596 temporary agents appointed out of 596 temporary agents authorised under the Union budget (compared to 591 authorised posts in 2019); notes that, in addition, 197 contract agents and 32 seconded national experts worked for the Agency in 2020;

18. Welcomes the proposal to extend the Agency's mandate but expresses concern that the addition of significant new tasks and its increasing workload over the years has not been accompanied by corresponding increases in the Agency's staff and resources, and that such a shortage of staff puts the continuity of its operations under significant pressure at an already critical time;

19. Recommends, in particular, that sufficient additional resources be allocated to the Agency to improve its competence in the fight against medicine shortages; invites the Commission to evaluate in detail the feasibility of granting the Agency additional capacity to manage shortages, including by means of the desired future transformation of the European Shortages Monitoring Platform into a proper and effective common European database;

20. Notes the gender balance in the Agency's senior management, with 16 out of 26 (61,54%) being men, and the gender balance in the Agency's management board, with 40 out of 65 (61,54%) being men; further notes the gender balance among the Agency's overall staff, with 536 out of 802 (66,83%) being women;

21. Notes that the Court found a weakness in the Agency's process for appointing selection panels for recruitment; welcomes the measures the Agency has taken to address this issue;

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

23. Welcomes the efforts made in the Agency's staff policy to promote teleworking and a healthy lifestyle; calls on the Agency to closely monitor the workload burden allocated to staff, especially under exceptional peak periods related to COVID-19; calls on the Agency to undertake measures to the extent possible to ensure staff's well-being and to have anti-burnout and anti-harassment policies in place; continues to encourage the Agency to pursue the development of a long term human resources policy framework that, addresses work-life balance, lifelong guidance and career development, gender balance, teleworking, geographical balance and the recruitment and integration of people with disabilities; acknowledges the efforts already made by the Agency in this regard; calls on the Agency to report on staff well-being for the discharge of the 2021 financial year;

24. Notes that, according to the 2018 follow-up report and the Court's 2019 report, the Agency has still not fully implemented the Court's recommendation on the use of external consultants; welcomes, however, the efforts of the Agency in 2020 to follow up on this observation by significantly decreasing the use of IT consultants;

25. Notes that the COVID-19 pandemic dominated the Agency's activities in 2020 which resulted in substantial resources being allocated to respond to the public health crisis; notes that, as a consequence, the scope of the Agency's 2020 work programme had to be reduced, with important public health activities either delayed or suspended, in line with the business continuity plan, such as clinical data publication for non-COVID-19 related products and the development of guidelines for and provision of support to scientific working parties; notes with concern the words of the former executive director of the Agency who stated that he was 'very concerned' about the redeployment of the Agency's staff, emphasising that the pressure under which his staff operated could not last forever; notes that the granting of 40 temporary agent posts by the budgetary authority helped the Agency to respond to the exceptional workload; further notes the Agency's statement that those positions were only granted in November 2020, when it was operationally too late to significantly mitigate the COVID-19 related workload of the year;

***Procurement***

26. Notes the Agency's reply to the follow-up observation from the Court's report of last year regarding the combination of unrelated items (provision of printers and management of the loading bay) in a single lot for tender for a framework contract, that it would have been unpractical and inefficient to put those services out to tender in isolation; notes that, following input from the Advisory Committee on Procurement and Contracts, the Agency's contract duration scheme for the aforementioned framework contract became 4+1+1, meaning that after four years the contract could be ended if needed; calls on the Agency to check for compatibility of combined services by including a tender strategy that is supported by market analysis as part of each procurement procedure, and to take that strategy into account during the tendering phase, and to keep the discharge authority informed about the developments in this regard;

27. Notes, with regard to the follow-up to last year's discharge observations, that the Agency signed a framework contract in 2019 with three companies for the supply of temporary workers without providing any breakdown of the estimated gross staff cost for the interim agents in each requested staff category; notes that, as a result, the Agency was not in a position to evaluate whether the service provider's mark-up or gross profit was reasonable in relation to similar contracts; acknowledges that the Agency has contacted the EU Agencies Network and has carried out market research to understand the local market conditions for contracted workers; calls on the Agency to communicate with the Court so that the Agency can determine which actions would be appropriate to address those findings;

***Prevention and management of conflicts of interest, and transparency***

28. Stresses that despite the majority of its funding coming from private sources, the Agency is a public authority; underlines that the perception of the Agency's independence and integrity is crucial and that therefore there is a need to ensure a high degree of transparency in all its activities to avoid regulatory capture and ensure citizens maintain their faith in the marketing authorisation system in the Union;

29. Welcomes the revised policy on the handling of competing interests of the management

board, which took effect from 1 July 2020 and the practice of systematic ex-ante controls on all declarations of interest submitted by management board members together with the requirement that those members undertake training before their declaration of interest can be submitted;

30. Notes with satisfaction the exceptional transparency measures the Agency implemented with regard to medicines for COVID-19, including accelerated publication timelines for clinical data and providing more information to the general public, such as publication of the product information with details of the conditions of use, at the time of the positive opinion of the Committee for Medicinal Products for Human Use on the marketing authorisation application; publication of the full European public assessment report , within three days of authorisation by the Commission; publication of clinical data submitted to the Agency in support of the applications for COVID-19 medicines after the authorisation of a medicine and once personal data have been anonymised; and the publication of the full risk management plan for authorised COVID-19 medicines; invites the Agency to apply the same transparency measures to all products regulated by the Agency;

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 2020, no internal whistleblowing case was reported, however, 25 reports of external whistleblowing cases were received; notes that 15 cases were closed and 10 cases are still ongoing; calls on the Agency to report to the discharge authority on the progress in those cases;

32. Welcomes the Agency's efforts to increase the level of transparency of its decision-making, as evidenced, for example, by the publication of data from clinical trials submitted in the marketing authorisation process for COVID-19 medicines or the increased level of communication with the media and the public; considers that this transparent approach is crucial in the current situation;

33. Notes with satisfaction that in 2020 no case of conflict of interest was reported by the Agency and that the Agency published the conflict 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;

34. Welcomes the further steps taken in order to enhance the transparency of the Agency's activities by reporting the meetings that the Agency's staff have with external stakeholders and their availability on the website of the Agency; notes the substantial and consistent concerns about the lack of transparency about vaccine contracts with pharmaceutical companies, but emphasises that although the Agency approves of those vaccines the Commission and not the Agency is a party in those contracts;

***Internal control***

35. 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 the internal control procedures are considered to provide reasonable assurance that the resources under the responsibility of the executive director

were used for their intended purposes and in accordance with the principles of sound financial management;

36. Notes the Court's observation related to the amendment of prices for a catering and restaurant services framework contract that only allowed the amendment to be made in 2021 and that the 2020 price revision was deemed irregular by the Court; further notes that, for one audited payment of EUR 125 954, the Agency could not reconcile the charged costs with the provisions and rates set out in the framework contract, thereby contravening the Financial Regulation; notes that both observations point to internal control weaknesses, which should be addressed in the annual assessment of the internal control framework; calls on the Agency to include the Court's findings in its annual assessment and to report to the discharge authority on the outcome of the assessment;

***COVID-19 response and business continuity***

37. Notes that, following the outbreak of COVID-19, the Agency invoked 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; notes that the Agency monitored closely the developments concerning various dimensions of the pandemic impact and followed the guidance and decisions made by the Commission, by the government of the Netherlands, which is the host Member State, and by health organisations such as the ECDC and the World Health Organization;

38. Notes that the Agency waived fees for provision of scientific advice to pharmaceutical companies developing COVID-19 treatments and vaccines, in order to facilitate research concerning the COVID-19 virus in 2020; notes, however, that the Agency did not experience an impact on its revenue estimates, as the fees waived were not part of the initial budget estimations;

***Other comments***

39. Notes, regarding the follow-up to last year's statement of assurance and the emphasis of matter paragraph in the Court's report in 2020, that the Agency is concerned about the lease and sublease agreement of its former premises in London which lasts until 2039; welcomes the fact that the Agency's management board has requested the Commission to work on this issue at the political level since the matter was not resolved during the negotiations relating to the withdrawal of the United Kingdom from the Union; notes with concern that the activities linked to the lease and sublease agreement are resource-intensive and lie outside the Agency's public health responsibilities; further notes that the current volatility of the United Kingdom and the global economy, caused inter alia by the COVID-19 pandemic, accentuate the urgency of the need for a fast resolution of the matter so as to allow the Agency to fully dedicate its resources to fighting the public health crisis and to focus its efforts on its public health mission;

40. Recognises the progress the Agency has achieved in developing information and communication technology systems enabling efficient medicines authorisation and monitoring, as well as implementation of recent Union law such as Regulation (EU) No

536/2014 [4] and Regulation (EU) 2019/6[5];

41. Notes with regret that the Agency was the victim of a cyberattack in December 2020; notes that a full criminal investigation was undertaken by law enforcement authorities, in cooperation with CERT-EU and Europol, as well as an external third-party service provider with specific expertise in IT security-incident response; notes that the Agency's defensive cybersecurity capabilities have been enhanced since then, with further investment to protect the Agency from future attacks; welcomes the efforts made by the Agency and calls on the Agency to also take account of the reputational risks and the destabilising effects on public opinion when information obtained through such an attack is abused; calls on the Agency to further strengthen its cybersecurity policy and report back in that regard to the discharge authority;

42. Highlights the importance of increasing the digitalisation of the Agency in terms of internal operation and management but also the importance of speeding up the digitalisation of procedures; stresses the need for the Agency to continue to be proactive in this regard in order to avoid, at all costs, a digital gap between the agencies;

43. Welcomes the fact that the Agency joined the initiative launched by EFSA to explore the potential of artificial intelligence (AI) in different areas of the Agencies' work, such as forecasting, automated reporting, image processing, content sanitisation, and expert identification; calls on the Agency to continue its efforts in this initiative in the coming years and asks the Agency to report back on its experience regarding the use of AI in its work;

44. Notes that the Agency developed and implemented a communication plan for 2020 that aimed to broaden the reach of its communication activities, especially those related to the unprecedented situation of the COVID-19 pandemic;

45. Welcomes the efforts made by the Agency to put in place a comprehensive strategy for sustainable development, including steps to reduce $CO_2$ emissions and energy consumption and to ensure that the Agency is a cost-effective and environment-friendly working place; encourages the Agency to further strengthen its efforts for sustainability; calls on the Agency to report to the discharge authority on the developments in this regard;

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46. Refers, for other observations of a cross-cutting nature accompanying its decision on discharge, to its resolution of [...] 2022[6] on the performance, financial management and control of the agencies.

[4] 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).
[5] 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).
[6] Texts adopted, P9_TA(2022)0000.

17.1.2022

# 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 2020
(2021/2132(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. Emphasises the important role of the European Medicines Agency ( ‘EMA') in protecting and promoting public and animal health by making independent, science-based recommendations on the quality, safety and efficacy of medicines, and providing scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;

2. Notes that following its relocation in 2019, EMA had planned to resume full-scale activities in 2020, however, the COVID-19 outbreak forced a re-prioritisation of its operations to tackle the pandemic; stresses that 2020 was consequently an extremely challenging year for EMA, requiring extreme agility and resilience to be able to maintain its activities while also supporting enhanced collaboration between Member States to manage the supply of medicines and global efforts to combat the pandemic in a new and challenging environment;

3. Recognises the contribution made by EMA in giving six medicines a recommendation for marketing authorisation following an accelerated assessment, thirteen medicines a recommendation for a conditional marketing authorisation, and authorising five medicines under exceptional circumstances;

4. Notes that EMA's final budget for the financial year 2020 was EUR 369 749 000, representing an increase of 6,63% compared to 2019;

5. Observes that the EMA is a fee-funded agency, with 84,22% of its funding derived from the evaluation of medicines and other business-related activities, 15,65% stemming from the Union budget and 0,13 % from various other sources;

6. Stresses that despite the majority of its funding coming from private sources, EMA is a public authority; underlines that the perception of the EMA’s independence and integrity is crucial and that therefore there is a need to ensure a high degree of transparency in all its activities to avoid regulatory capture and ensure citizens maintain their faith in the marketing authorisation system in the Union;

7. Notes EMA’s decision to waive all fees for scientific advice applications from developers of potential COVID-19 therapeutics or vaccines, as of 13 March 2020, and welcomes the waiving of all fees for provision of scientific advice to academic researchers developing orphan medicines from 19 June 2020; believes that other instances of waiving fees subject to specific criteria set out by EMA, in particular regarding SMEs, should follow;

8. Notes with satisfaction that all of the 596 authorised posts were occupied on 31 December 2020, compared to 583 posts out of 591 in 2019;

9. Is pleased that EMA successfully maintained the quality and continuity of its operations whilst relocating its seat to its final premises in Amsterdam following the United Kingdom’s withdrawal from the Union; notes that potential liabilities arising from the lease on EMA’s former office premises in London remain a matter of concern; recognises that EMA was able to respond effectively to the workload associated with the COVID-19 pandemic and welcomes EMA’s work on facilitating access to new vaccines and therapeutics to treat and prevent the spread of COVID-19;

10. Highlights the fact that, in 2020, EMA recommended 97 new human medicines for marketing authorisation, including 39 new active substances, and 20 new veterinary medicines, including 13 new active substances;

11. Welcomes the proposal to extend EMA’s mandate but expresses concern that the addition of significant new tasks and its increasing workload over the years has not been accompanied by 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 at an already critical time;

12. Recommends, in particular, that sufficient additional resources be allocated to EMA to improve its competence in the fight against medicine shortages; invites the Commission to evaluate in detail the feasibility of granting EMA additional capacity to manage shortages, including by means of the desired future transformation of the European Shortages Monitoring Platform into a proper and effective common European database;

13. Welcomes the revised policy on the handling of competing interests of the management board, which took effect from 1 July 2020 and the practice of systematic ex-ante controls on all declarations of interest submitted by management board members together with the requirement that those members undertake training before their declaration of interest can be submitted;

14. Notes with satisfaction the exceptional transparency measures EMA implemented with regard to medicines for COVID-19, including accelerated publication timelines for clinical data and providing more information to the general public such as publication of the product information with details of the conditions of use at the time of the positive opinion of the Committee for Medicinal Products for Human Use (CHMP) on the marketing authorisation application; publication of the full European public assessment report (EPAR), within three days of authorisation by the Commission; publication of clinical data submitted to EMA in support of the applications for COVID-19 medicines after the authorisation of a medicine and once personal data have been anonymised; and the publication of the full risk management plan for authorised COVID-19 medicines;

invites EMA to apply the same transparency measures to all products regulated by EMA;

15. Recognises the progress EMA has achieved in developing information and communication technology systems enabling efficient medicines authorisation and monitoring, as well as implementation of new Union law such as Regulation (EU) No 536/2014 [1] and Regulation (EU) 2019/6[2];

16. Notes that the Court found a weakness in EMA's process for appointing selection panels for recruitment; welcomes the measures EMA has taken to address this issue;

17. Notes, with concern, that the Court identified public procurement weaknesses as well as irregularities in a catering and restaurant services framework contract, including a failure to verify that the amounts invoiced were correct;

18. Notes with satisfaction that 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 the purpose of monitoring vaccine safety and reporting side effects, as well as with regard to antimicrobial consumption and resistance;

19. Highlights the importance of involving the relevant stakeholders, such as representatives of health professionals, of patients and of other parties, in the light of the alarming prevalence of disinformation regarding the COVID-19 pandemic in public debate on protection of public health and calls on EMA to continue to contribute to such debate as actively as possible, based on the latest scientific knowledge;

20. Welcomes the fact that tackling increasing antimicrobial resistance (in particular through supporting the development of new medicines, collecting data on veterinary antimicrobial consumption and promoting responsible use of antimicrobial medicines) remains one of EMA’s priorities, even in the light of the current situation;

21. Emphasises that the COVID-19 pandemic is impacting all aspects of health care, including the availability of medicines due to supply chain disruptions; considers that the situation has only served to highlight the need, of which we were already aware, for the Union to reach the highest possible level of self-sufficiency in the development and production of medicines; welcomes the EMA’s commitment to continue contributing to the development and strengthening of the Union’s response system in the event of reduced availability of medicines;

22. Welcomes the level of assistance that EMA has provided to companies developing vaccines and medicines against COVID-19; lauds its consistently scientific approach, which places the health of Union citizens above all else;

23. Welcomes the EMA’s efforts to increase the level of transparency of its decision-making, as evidenced, for example, by the publication of data from clinical trials submitted in the marketing authorisation process for COVID-19 medicines or the

[1] 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).
[2] 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).

increased level of communication with the media and the public; considers that this transparent approach is crucial in the current situation;

24. Welcomes the fact that the Court has stated that it has obtained reasonable assurance that the EMA’s annual accounts for 2020 are reliable and that the underlying transactions are legal and regular;

25. 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 2020.

## INFORMATION ON ADOPTION IN COMMITTEE ASKED FOR OPINION

| | |
|---|---|
| **Date adopted** | 13.1.2022 |
| **Result of final vote** | +: 68<br>–: 7<br>0: 3 |
| **Members present for the final vote** | Bartosz Arłukowicz, Margrete Auken, Simona Baldassarre, Marek Paweł Balt, Traian Băsescu, Aurélia Beigneux, Monika Beňová, Sergio Berlato, Alexander Bernhuber, Malin Björk, Simona Bonafè, Delara Burkhardt, Pascal Canfin, Sara Cerdas, Mohammed Chahim, Tudor Ciuhodaru, Nathalie Colin-Oesterlé, Esther de Lange, Christian Doleschal, Bas Eickhout, Cyrus Engerer, Eleonora Evi, Agnès Evren, Pietro Fiocchi, Andreas Glück, Catherine Griset, Jytte Guteland, Teuvo Hakkarainen, Anja Hazekamp, Martin Hojsík, Pär Holmgren, Jan Huitema, Yannick Jadot, Adam Jarubas, Petros Kokkalis, Athanasios Konstantinou, Ewa Kopacz, Joanna Kopcińska, Peter Liese, Sylvia Limmer, Javi López, César Luena, Fulvio Martusciello, Liudas Mažylis, Joëlle Mélin, Tilly Metz, Giuseppe Milazzo, Silvia Modig, Dolors Montserrat, Alessandra Moretti, Dan-Ştefan Motreanu, Ville Niinistö, Ljudmila Novak, Grace O'Sullivan, Jutta Paulus, Stanislav Polčák, Jessica Polfjärd, Luisa Regimenti, Frédérique Ries, María Soraya Rodríguez Ramos, Sándor Rónai, Rob Rooken, Silvia Sardone, Christine Schneider, Günther Sidl, Ivan Vilibor Sinčić, Linea Søgaard-Lidell, Maria Spyraki, Nicolae Ştefănuță, Nils Torvalds, Edina Tóth, Véronique Trillet-Lenoir, Petar Vitanov, Alexandr Vondra, Mick Wallace, Pernille Weiss, Emma Wiesner, Tiemo Wölken, Anna Zalewska |
| **Substitutes present for the final vote** | Danilo Oscar Lancini, Demetris Papadakis |

## FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

| 68 | + |
|---|---|
| ECR | Sergio Berlato, Pietro Fiocchi, Joanna Kopcińska, Giuseppe Milazzo, Alexandr Vondra, Anna Zalewska |
| NI | Edina Tóth |
| PPE | Bartosz Arłukowicz, Traian Băsescu, Alexander Bernhuber, Nathalie Colin-Oesterlé, Christian Doleschal, Agnès Evren, Adam Jarubas, Ewa Kopacz, Esther de Lange, Peter Liese, Fulvio Martusciello, Liudas Mažylis, Dolors Montserrat, Dan-Ştefan Motreanu, Ljudmila Novak, Stanislav Polčák, Jessica Polfjärd, Luisa Regimenti, Christine Schneider, Pernille Weiss |
| Renew | Pascal Canfin, Andreas Glück, Martin Hojsík, Jan Huitema, Frédérique Ries, María Soraya Rodríguez Ramos, Nicolae Ştefănuță, Linea Søgaard-Lidell, Nils Torvalds, Emma Wiesner |
| S&D | Marek Paweł Balt, Monika Beňová, Simona Bonafè, Delara Burkhardt, Sara Cerdas, Mohammed Chahim, Tudor Ciuhodaru, Cyrus Engerer, Jytte Guteland, Javi López, César Luena, Alessandra Moretti, Demetris Papadakis, Sándor Rónai, Günther Sidl, Petar Vitanov, Tiemo Wölken |
| The Left | Malin Björk, Anja Hazekamp, Petros Kokkalis, Silvia Modig, Mick Wallace |
| Verts/ALE | Margrete Auken, Bas Eickhout, Eleonora Evi, Pär Holmgren, Yannick Jadot, Tilly Metz, Ville Niinistö, Grace O'Sullivan, Jutta Paulus |

| 7 | - |
|---|---|
| ECR | Rob Rooken |
| ID | Aurélia Beigneux, Catherine Griset, Teuvo Hakkarainen, Sylvia Limmer, Joëlle Mélin |
| NI | Ivan Vilibor Sinčić |

| 3 | 0 |
|---|---|
| ID | Simona Baldassarre, Danilo Oscar Lancini, Silvia Sardone |

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

## INFORMATION ON ADOPTION IN COMMITTEE RESPONSIBLE

| | |
|---|---|
| **Date adopted** | 31.3.2022 |
| **Result of final vote** | +: 26<br>–: 3<br>0: 1 |
| **Members present for the final vote** | Matteo Adinolfi, Gilles Boyer, Olivier Chastel, Caterina Chinnici, Lefteris Christoforou, Corina Crețu, Ryszard Czarnecki, José Manuel Fernandes, Raffaele Fitto, Luke Ming Flanagan, Isabel García Muñoz, Monika Hohlmeier, Jean-François Jalkh, Pierre Karleskind, Mislav Kolakušić, Joachim Kuhs, Ryszard Antoni Legutko, Claudiu Manda, Alin Mituța, Jan Olbrycht, Younous Omarjee, Markus Pieper, Michèle Rivasi, Petri Sarvamaa, Angelika Winzig, Lara Wolters, Tomáš Zdechovský |
| **Substitutes present for the final vote** | Bas Eickhout, Tsvetelina Penkova, Viola Von Cramon-Taubadel |

## FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

| 26 | + |
|---|---|
| ECR | Ryszard Czarnecki, Raffaele Fitto, Ryszard Antoni Legutko |
| PPE | Lefteris Christoforou, José Manuel Fernandes, Monika Hohlmeier, Jan Olbrycht, Markus Pieper, Petri Sarvamaa, Angelika Winzig, Tomáš Zdechovský |
| Renew | Gilles Boyer, Olivier Chastel, Pierre Karleskind, Alin Mituța |
| S&D | Caterina Chinnici, Corina Crețu, Isabel García Muñoz, Claudiu Manda, Tsvetelina Penkova, Lara Wolters |
| The Left | Luke Ming Flanagan, Younous Omarjee |
| Verts/ALE | Bas Eickhout, Michèle Rivasi, Viola Von Cramon-Taubadel |

| 3 | - |
|---|---|
| ID | Jean-François Jalkh, Joachim Kuhs |
| NI | Mislav Kolakušić |

| 1 | 0 |
|---|---|
| ID | Matteo Adinolfi |

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