AMENDMENTS
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Draft report
Tomáš Zdechovský
(PE698.974v02-00)

2020 discharge: European Medicines Agency
(2021/2132(DEC))
Amendment 1
Katalin Cseh, Ramona Strugariu, Olivier Chastel, Pierre Karleskind, Michal Wiezik, Alin Mituța, Gilles Boyer

Motion for a resolution
Recital A

Motion for a resolution

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 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;

\(^1\) OJ C 114, 31.3.2021, p.25.

Amendment

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;

\(^1\) OJ C 114, 31.3.2021, p.25.

Or. en

Amendment 2
Bas Eickhout
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 2

Motion for a resolution

2. Notes that, despite the difficulties caused by the global pandemic, the Agency continued to act in the interests of 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

Amendment

2. Notes that, despite the unprecedented difficulties since the start of the global 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
such products; 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 swift preparatory work related to the certification of the vaccines;

Or. en

Amendment 3
Katalin Cseh, Ramona Strugariu, Olivier Chastel, Pierre Karleskind, Michal Wiezik, Alin Mituța, Gilles Boyer

Motion for a resolution  
Paragraph 2

2. Notes that, despite the difficulties caused by the global pandemic, the Agency continued to act in the interests of 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; praises the Agency for its efforts to effectively analyse and to quickly approve vaccines against COVID-19 in the Member States;

Or. en

Amendment 4
Bas Eickhout  
on behalf of the Greens/EFA Group

Motion for a resolution  
Paragraph 2 a (new)

2 a. Emphasises that despite the Agency’s hard work in 2020, the COVID-19 pandemic challenged the existing
public health security infrastructure, including the need for strengthening the capabilities of the Agency 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 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\(^a\), the communication of the Commission of 25 November 2020 entitled ‘Pharmaceutical Strategy for Europe’, and Regulation (EU) 2022/123\(^b\); 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 Agency has enough resources to implement its expanded mandate effectively;


Or. en

Amendment 5
Joachim Kuhs, Jean-François Jalkh
Motion for a resolution  
Paragraph 2 a (new)

Motion for a resolution  
Amendment

2 a.  Regrets that the Agency disregarded repositioning of well-known medicines to treat COVID-19 and advices against some of them when the benefit-risks balance was not bad in comparison to new vaccines’ one;

Or. en

Amendment 6  
Joachim Kuhs, Matteo Adinolfi, Jean-François Jalkh

Motion for a resolution  
Paragraph 2 b (new)

Motion for a resolution  
Amendment

2 b.  Regrets that not everything has been done to rapidly validate all available therapeutic options in the fight against COVID-19;

Or. en

Amendment 7  
Joachim Kuhs, Jean-François Jalkh

Motion for a resolution  
Paragraph 2 c (new)

Motion for a resolution  
Amendment

2 c.  Exhorts the Agency to publish the integrality of data submitted by the applicants for vaccines against COVID-19;

Or. en
Amendment 8
Katalin Cseh, Ramona Strugariu, Olivier Chastel, Pierre Karleskind, Michal Wiezik, Alin Mituța, Gilles Boyer

Motion for a resolution
Paragraph 4 a (new)

Motion for a resolution

4 a. 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;

Or. en

Amendment 9
Bas Eickhout
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 5

Motion for a resolution

5. Notes 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;

Amendment

5. Welcomes 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;

Or. en

Amendment 10
Katalin Cseh, Ramona Strugariu, Olivier Chastel, Pierre Karleskind, Michal Wiezik, Alin Mituța, Gilles Boyer
Motion for a resolution
Paragraph 6 a (new)

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

Amendment 11
Katalin Cseh, Ramona Strugariu, Olivier Chastel, Pierre Karleskind, Michal Wiezik, Alin Mituţa, Gilles Boyer

Motion for a resolution
Paragraph 6 b (new)

6 b. Welcomes the efforts made in staff policy to promote teleworking and healthy life and continues to encourage the Agency to pursue the development of a long term human resources policy framework that addresses the work-life balance, the lifelong guidance and career development, the gender balance, the teleworking, the geographical balance and the recruitment and integration of people with disabilities;

Amendment 12
Bas Eickhout
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 9

9. 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, development of guidelines for and provision of support to scientific working parties; 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;

Amendment 13
Bas Eickhout
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 9 a (new)

Motion for a resolution

9 a. Calls on the Agency to closely monitor 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; calls on the Agency to report on staff well-being for
the discharge of the 2021 financial year;

Amendment 14
Joachim Kuhs, Matteo Adinolfi, Jean-François Jalkh

Motion for a resolution
Paragraph 10 a (new)

Motion for a resolution

10 a. Asks the Agency for more details concerning the situation around the tender EMA/2019/38/LD$^{1a}$ aiming to sign 'multiple supplier framework contracts in cascade for the provision of legal advice, pre-litigation and litigation services in relation to debt recovery matters. In particular, the services to be provided under this framework contract shall entail legal assistance, legal representation and adjudication to cover pre-litigation and litigation proceedings with respect to debt recovery enforcement matters'; asks for budgetary and legal clarifications regarding the mentioned debt;

$^{1a}$

Amendment 15
Joachim Kuhs

Motion for a resolution
Paragraph 12 a (new)

Motion for a resolution

12 a. Draws attention to the case 2012/2020/MIG opened by the European Ombudsman related to the 'The European
Medicines Agency’s failure to reply to a request for public access to documents concerning the pathogen SARS-CoV-2; 


Amendment 16
Bas Eickhout
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 13

13. Notes that in 2020 no case of conflict of interest was reported by the Agency and that the Agency published the conflicts of interest declarations of its management board members and its senior management; notes with satisfaction that the Agency published the CVs of its management board members, senior management and of its external and in-house experts;

Amendment

13. Notes with satisfaction that in 2020 no case of conflict of interest was reported by the Agency and that the Agency published the conflicts of interest declarations of its management board members and its senior management; notes with satisfaction that the Agency published the CVs of its management board members, senior management and of its external and in-house experts;

Amendment 17
Bas Eickhout
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 14

14. 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

Amendment

14. 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; 

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 these vaccines the Commission and not the Agency is a party in these contracts;*

Amendment 18

Katalin Cseh, Ramona Strugariu, Olivier Chastel, Pierre Karleskind, Michal Wiezik, Alin Mituța, Gilles Boyer

Motion for a resolution

Paragraph 20

20. 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; 

Or. en

Amendment 19

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Motion for a resolution
Paragraph 20 a (new)

20 a. Recalls the importance to increase 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 at all costs;

Or. en

Amendment 20
Katalin Cseh, Ramona Strugariu, Olivier Chastel, Pierre Karleskind, Michal Wiezik, Alin Mituța, Gilles Boyer

Motion for a resolution
Paragraph 20 b (new)

20 b. Welcomes that the Agency joined the initiative launched by the European Food Safety Authority 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 following years and asks the Agency to report back on its experience regarding the use of AI in its work;

Or. en

Amendment 21
Katalin Cseh, Ramona Strugariu, Olivier Chastel, Pierre Karleskind, Michal Wiezik, Alin Mituța, Gilles Boyer

Motion for a resolution
Paragraph 21

Motion for a resolution

21. Welcomes the efforts made by the Agency to put in place a comprehensive strategy for sustainable development, including steps to reduce CO₂ emissions and ensure that the Agency is a cost-effective and environment-friendly working place; calls on the Agency to report to the discharge authority on the developments in this regard;

Amendment

21. Welcomes the efforts made by the Agency to put in place a comprehensive strategy for sustainable development, including steps to reduce CO₂ emissions and energy consumption and 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;

Or. en