European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2023/2156(DEC)

12.2.2024

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 general budget of the European Medicines Agency for the financial year 2022
(2023/2156(DEC))

Rapporteur for opinion: Pascal Canfin

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

2. Notes that the EMA's total final appropriations for 2022 amounted to EUR 421 815 000, representing a 11,22% increase compared to the 2021 budget,

3. Recalls that the EMA is a fee-funded agency, with 88,27 % of its 2022 revenue stemming from fees paid by the pharmaceutical industry for services provided, 11,70 % stemming from the Union budget and 0,02 % from various other sources; 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;

4. Notes with concern ongoing property-related obligations in regards to the Agencys former premises in London; takes good note of the fact that the Agency and its Management Board are concerned that the Agency must on top of its tasks also manage commercial property in a third country leading to a diversion of its human and financial resources from its public health responsibilities for the EU citizens; Notes with concern that this situation on subletting its former London premises will continue until 2039; takes note that on 31 December 2022, the total estimated outstanding rent, associated services charges and landlord insurance to be paid by the Agency up to the end of the lease term was €366 million; welcomes the efforts of the Agency to sublet its former premises since July 2019 to a company belonging to the WeWork group; notes with concern the uncertainties surrounding the financial performance of the WeWork group which, on 6 November 2023, filed for Chapter 11 of the US Bankruptcy Code for its branches in the US and Canada. Acknowledges that subletting the Agency’s premises in a third country is not in line with its founding Regulation (EC) 726/2004 and that it requires the Agency to divert significant resources from its public health activities; notes that the situation has not been resolved after four years since the European Parliament first asked for a political resolution on the matter; urgently calls on the Commission to secure a long-term political resolution of this issue and to allow the Agency to fully focus its efforts on its public health mission;

5. Notes however that inadequate resources for the EMA may undermine the ability of the Agency to deliver on its mission and calls on the Commission and Council to allocate adequate EU funding to ensure the Agency has enough resources to carry out all of its activities on the wide range of regulatory mechanisms including facilitating the development and access to medicines, supporting research and innovation and its responsibilities for monitoring and mitigating potential or actual shortages of critical

medicines without any delay;

6. Notes that 658 of the 662 authorised posts were occupied on 31 December 2022, compared to the 644 posts out of 657 in 2021;

7. Welcomes the extension of the EMA's mandate; underlines that this addition of new tasks and its increasing workload needs to be accompanied by adequate corresponding increases in the staff and resources, and that a shortage of staff puts the continuity of its operations under significant pressure and threatens the quality of the EMA's work.

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

9. Notes that EMA recommended in 2022 marketing authorisation for 89 new human medicines, including 41 new active substances, and 10 new veterinary medicines, including 3 new active substances and 2 vaccines; 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;

10 Welcomes the fact that, following the cyberattack in December 2020, EMA has taken various measures to further enhance its cybersecurity capabilities, including the establishment in 2021-2022 of the Information Security Management Steering Committee, a senior-level governance board with the primary responsibility to oversee the implementation of the Agency's Information Security Strategy;

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

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 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; notes that in November 2022, EMA activated a new Joint 3Rs Working Party of the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Veterinary Medicinal Products (CVMP).

14. 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; welcomes the announcement for a phased restart of clinical data publication for centrally authorised medicines beyond the scope of COVID-19. 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;

15. Calls on the Commission to ensure that EMA receives adequate resources to implement the tasks that were assigned to the Agency by adoption of the Clinical Trials Regulation and avoid staff shortages that will 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;

16 Welcomes EMA's implementation of the EU Regulation 2019/6 on Veterinary Medicinal Products Regulation, aiming to boost innovation and increase availability of safe and high-quality veterinary medicines for treating and preventing animal diseases, as well as the implementation of the EU Regulation 536/2014 on Clinical Trials;

17. Welcomes the fact that the Court of Auditors has stated that it has obtained reasonable assurances that the EMA's annual accounts for 2022 are reliable and that the underlying transactions are legal and regular;

18. Notes that in March, the EMA started to operate under a new extended mandate which recognises the role played by the Agency during the pandemic and gives it additional responsibilities in the area of coordination and crisis response; notes, in this context, that it is essential to ensure funding commensurate with this extended mandate in the future;

19. Notes that this extended mandate also provides the framework for the creation of DARWIN EU, a model for gathering real evidence from across the EU on diseases, populations and the use and efficacy of medicines and vaccines throughout their lifecycle; sees this as a potentially major change in medicines regulation;

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

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

22. 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 2022.

ANNEX: ENTITIES OR PERSONS FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT

The Chair in his capacity as rapporteur has received input from the following entities or persons in the preparation of the opinion:

Entity and/or person
European Medicines Agency

The list above is drawn up under the exclusive responsibility of the Chair in his capacity as rapporteur.

INFORMATION ON ADOPTION IN COMMITTEE ASKED FOR OPINION

Date adopted	24.1.2024
Result of final vote	+: 67 –: 9 0: 9
Members present for the final vote	Catherine Amalric, Maria Arena, Hildegard Bentele, Sergio Berlato, Michael Bloss, Delara Burkhardt, Pascal Canfin, Sara Cerdas, Mohammed Chahim, Nathalie Colin-Oesterlé, Maria Angela Danzì, Esther de Lange, Christian Doleschal, Bas Eickhout, Pietro Fiocchi, Heléne Fritzon, Malte Gallée, Gianna Gancia, Catherine Griset, Teuvo Hakkarainen, Anja Hazekamp, Martin Hojsík, Jan Huitema, Karin Karlsbro, Petros Kokkalis, Peter Liese, Javi López, César Luena, Elżbieta Katarzyna Łukacijewska, Marian-Jean Marinescu, Lydie Massard, Liudas Mažylis, Marina Mesure, Silvia Modig, Dolors Montserrat, Alessandra Moretti, Ville Niinistö, Ljudmila Novak, Nikos Papandreou, Francesca Peppucci, Stanislav Polčák, Jessica Polfjärd, Erik Poulsen, Nicola Procaccini, Frédérique Ries, María Soraya Rodríguez Ramos, Maria Veronica Rossi, Silvia Sardone, Günther Sidl, Ivan Vilibor Sinčić, Maria Spyraki, Edina Tóth, Achille Variati, Petar Vitanov, Alexandr Vondra, Mick Wallace, Emma Wiesner, Michal Wiezik
Substitutes present for the final vote	Asger Christensen, Christophe Clergeau, Margarita de la Pisa Carrión, Martin Häusling, Billy Kelleher, Ska Keller, Danilo Oscar Lancini, Sara Matthieu, Dace Melbārde, Marlene Mortler, Manuela Ripa, Idoia Villanueva Ruiz
Substitutes under Rule 209(7) present for the final vote	Mazaly Aguilar, Katarina Barley, Daniel Buda, Ana Collado Jiménez, Marie Dauchy, Matthias Ecke, Paola Ghidoni, Peter Jahr, Thierry Mariani, Nora Mebarek, Sara Skyttedal, Michaela Šojdrová, Veronika Vrecionová, Thomas Waitz, Stefania Zambelli

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

67	+
ECR	Mazaly Aguilar, Pietro Fiocchi, Nicola Procaccini, Alexandr Vondra, Veronika Vrecionová
NI	Maria Angela Danzì, Edina Tóth
PPE	Hildegard Bentele, Daniel Buda, Nathalie Colin-Oesterlé, Ana Collado Jiménez, Christian Doleschal, Peter Jahr, Esther de Lange, Peter Liese, Elżbieta Katarzyna Łukacijewska, Marian-Jean Marinescu, Liudas Mažylis, Dace Melbārde, Dolors Montserrat, Marlene Mortler, Ljudmila Novak, Francesca Peppucci, Stanislav Polčák, Jessica Polfjärd, Sara Skyttedal, Michaela Šojdrová, Maria Spyraki, Stefania Zambelli
Renew	Catherine Amalric, Pascal Canfin, Asger Christensen, Martin Hojsík, Jan Huitema, Karin Karlsbro, Billy Kelleher, Erik Poulsen, Frédérique Ries, María Soraya Rodríguez Ramos, Emma Wiesner, Michal Wiezik
S&D	Maria Arena, Katarina Barley, Delara Burkhardt, Sara Cerdas, Mohammed Chahim, Christophe Clergeau, Matthias Ecke, Heléne Fritzon, Javi López, César Luena, Nora Mebarek, Alessandra Moretti, Nikos Papandreou, Günther Sidl, Achille Variati, Petar Vitanov
Verts/ALE	Michael Bloss, Bas Eickhout, Malte Gallée, Martin Häusling, Ska Keller, Lydie Massard, Sara Matthieu, Ville Niinistö, Manuela Ripa, Thomas Waitz

9	-
ECR	Teuvo Hakkarainen
ID	Marie Dauchy, Catherine Griset, Thierry Mariani
NI	Ivan Vilibor Sinčić
The Left	Petros Kokkalis, Marina Mesure, Idoia Villanueva Ruiz, Mick Wallace

9	0
ECR	Sergio Berlato, Margarita de la Pisa Carrión
ID	Gianna Gancia, Paola Ghidoni, Danilo Oscar Lancini, Maria Veronica Rossi, Silvia Sardone
The Left	Anja Hazekamp, Silvia Modig

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