European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2021/2132(DEC)

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

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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. 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 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

[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).

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 –: 7 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