



2017/2154(DEC)

25.1.2018

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 2016
(2017/2154(DEC))

Rapporteur: Adina-Ioana Vălean

PA_NonLeg

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. Recalls that, as stipulated in its financial regulation, budget revenue of the European Medicines Agency ('the Agency') is based on cash received for contributions from the Union, fees for marketing authorisation applications for pharmaceutical products and for post-authorisation activities as well as for various administrative activities;
2. Notes that in 2016 the total budget of the Agency was EUR 308 422 000; highlights that 89,4 % of the Agency's revenue came from fees paid by the pharmaceutical industry for services provided, 5,5 % from the Union budget and 5 % from external assigned revenue;
3. Points out that the Agency monitors budget spending through a robust monitoring process;
4. Reiterates the important role of the Agency in protecting and promoting public and animal health by assessing and supervising medicines for human or veterinary use;
5. Notes that in 2016 the Agency recommended 92 new medicines for marketing authorisation (81 human, 11 veterinary) and that those include 33 new active substances (27 human, 6 veterinary); stresses that those substances have previously never been authorised in a medicine in the Union and are not related to the chemical structure of any other authorised substance;
6. Welcomes the launch of the clinical data website in October 2016, which represents an important step towards higher transparency; notes that the website gives open access to clinical reports for new medicines for human use authorised in the Union; notes that the Agency is the first regulatory authority worldwide to provide such broad access to clinical data;
7. Notes that the Agency set up a taskforce dedicated to 'Brexit', which in 2016 was focused on assessing the impact of Brexit on the Agency, with the aim of identifying the main risks, and propose possible mitigating measures;
8. Notes that setting up a fully transparent reporting system is costly and complicated, owing to the complexity of that system and the significant number of transactions processed every year;
9. Stresses that the Agency was not allowed to create a 'Brexit' contingency reserve;
10. Is concerned that in the case of fee-funded agencies, like the Agency, the staff cuts imposed in recent years have meant a reduction in staff working on tasks that are actually funded by applicants' fees and not by the Union budget; that has been done without taking into consideration the extra workload created by increasing numbers of applications, nor the corresponding increase in income from fees paid by applicants for

the services provided, which could have allowed staff increases without any impact on the Union budget; notes that the need for additional staff and budget resources will become particularly acute for the Agency during the 2018-2020 preparation and relocation phase to its new seat, during which the Agency will have to continue fulfilling its key public health tasks as well as the additional tasks linked to the relocation itself;

11. Regrets that the publication for public consultation of the Agency's new approach towards transparency was put on hold due to the need to prioritise the Agency's Brexit preparedness;
12. Stresses that the policy on the handling of competing interests of scientific committees' members and experts was updated in October 2016; notes that it includes a clarification on the restrictions regarding experts' potential employment in a pharmaceutical company and aligns the rules relating to close family members' interests for scientific committee and working party members, with those for the Management Board members;
13. Highlights that the policy on competing interests for Management Board members came into effect in May 2016; notes moreover that a revised decision on the rules concerning the handling of declared interests of the Agency's staff members was adopted in October 2016;
14. Notes the Agency achieved occupancy rate of 98 % for temporary agents;
15. Recommends, on the basis of the facts available, that discharge be granted to the Executive Director of the European Medicines Agency with respect to the implementation of the Agency's budget for the financial year 2016.

INFORMATION ON ADOPTION IN COMMITTEE ASKED FOR OPINION

Date adopted	24.1.2018
Result of final vote	+: 41 -: 8 0: 0
Members present for the final vote	Marco Affronte, Pilar Ayuso, Ivo Belet, Simona Bonafè, Biljana Borzan, Paul Brannen, Soledad Cabezón Ruiz, Nessa Childers, Birgit Collin-Langen, Seb Dance, Stefan Eck, José Inácio Faria, Francesc Gambús, Elisabetta Gardini, Gerben-Jan Gerbrandy, Arne Gericke, Julie Girling, Françoise Grossetête, Andrzej Grzyb, Jytte Guteland, Anneli Jäätteenmäki, Karin Kadenbach, Urszula Krupa, Giovanni La Via, Peter Liese, Susanne Melior, Gilles Pargneaux, Piernicola Pedicini, Bolesław G. Piecha, John Procter, Julia Reid, Frédérique Ries, Daciana Octavia Sârbu, Renate Sommer, Claudiu Ciprian Tănăsescu, Ivica Tolić, Adina-Ioana Vălean, Jadwiga Wiśniewska, Damiano Zoffoli
Substitutes present for the final vote	Elena Gentile, Martin Häusling, Norbert Lins, Nuno Melo, Ulrike Müller, Christel Schaldemose, Bart Staes, Keith Taylor, Carlos Zorrinho
Substitutes under Rule 200(2) present for the final vote	Jiří Maštálka

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

41	+
ALDE	Gerben-Jan Gerbrandy, Anneli Jäätteenmäki, Ulrike Müller, Frédérique Ries
GUE/NGL	Stefan Eck, Jiří Maštálka
PPE	Pilar Ayuso, Ivo Belet, Birgit Collin-Langen, José Inácio Faria, Francesc Gambús, Elisabetta Gardini, Françoise Grossetête, Andrzej Grzyb, Giovanni La Via, Peter Liese, Norbert Lins, Nuno Melo, Renate Sommer, Ivica Tolić, Adina-Ioana Vălean
S&D	Simona Bonafè, Biljana Borzan, Paul Brannen, Soledad Cabezón Ruiz, Nessa Childers, Seb Dance, Elena Gentile, Jytte Guteland, Karin Kadenbach, Susanne Melior, Gilles Pargneaux, Christel Schaldemose, Daciana Octavia Sârbu, Claudiu Ciprian Tănăsescu, Damiano Zoffoli, Carlos Zorrinho
VERTS/ALE	Marco Affronte, Martin Häusling, Bart Staes, Keith Taylor

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ECR	Arne Gericke, Julie Girling, Urszula Krupa, Bolesław G. Piecha, John Procter, Jadwiga Wiśniewska
EFDD	Piernicola Pedicini, Julia Reid

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Key to symbols:

+ : in favour

- : against

0 : abstention