



Committee on the Environment, Public Health and Food Safety

2015/2171(DEC)

22.1.2016

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 (EMA) for the financial year 2014
(2015/2171(DEC))

Rapporteur: Giovanni La Via

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 the Financial Regulation, budget revenue of the European Medicines Agency ('the Agency') is based on cash received for contributions from the European Union, fees for marketing authorisation applications for pharmaceutical products and for post-authorisation activities as well as for various administrative activities;
2. Recalls that the Pharmacovigilance Fee Regulation¹ was published in the Official Journal of the European Union on 27 June 2014 and has applied to procedures starting from 26 August 2014, although annual fees to support information technology systems and literature monitoring activities will not be levied until 2015; likes to stress that that Regulation now allows the Agency to collect fees from marketing authorisation holders to finance these pharmacovigilance activities conducted at Union level in respect of medicinal products for human use; points out that the income is used to remunerate national competent authorities for the scientific assessment carried out by the rapporteurs of the EMA's Pharmacovigilance Risk Assessment Committee and contributes to the pharmacovigilance costs of the Agency;
3. Notes that authorised appropriations in the Agency's initial budget for 2014 totalled EUR 297 169 000 representing a 28,33% increase over the 2013 initial budget (EUR 231 560 000) and that two amending budgets were introduced in 2014 to account mainly for a decrease in revenue from services rendered of EUR 8 000 000 and a decrease in the Union contribution requested of EUR 6 000 000;
4. Notes that, as a result, the total resources available to the Agency in 2014 were EUR 282 474 000 representing a 12,3% increase compared to 2013, which is mainly due to the overall higher number of applications in 2014; notes that, of total revenue, 80,09% derived from the evaluation of medicines and other business related activities and that the Union contribution provided for about 11% of the revenue in 2014 (EUR 29 936 000 including a special contribution for orphan medicines fee reductions of EUR 9 432 100); would like to stress that this amount represents 0,021% of the overall Union budget;
5. Notes that, as far as commitment appropriations are concerned, an amount of EUR 7,6 million was never used by the Agency, due to the revision of the salaries weighting factor for the years 2011 and 2012 (EUR 6 million), and a correction of the 2012 accounts requested by the Court of Auditors, following which the Agency's 2012 outturn was more negative than planned; notes, further, that EUR 2 million could still be transferred as subsidy to another agency (Eurojust) leaving EUR 5,6 million not consumed;
6. Notes that, as regards payment appropriations, all 2014 appropriations were consumed,

¹ Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use (OJ L 189, 27.6.2014, p. 112).

and that the level of execution amounts to 95,8%, representing an amount of EUR 1,5 million in unused appropriations; that this under-execution corresponds to the unused assigned revenue (the Agency's outturn of 2013), which was reused in the year 2015;

7. Welcomes that 580 of 599 available posts had been filled by the end of 2014 and that 210 contract agents, seconded national experts and employment agency staff were employed by the Agency; welcomes that the occupation rate has increased compared to 2013; notes that the proportion of contract agents, seconded national experts and employment agency staff has increased compared to 2013; congratulates the Agency for dedicating about 79% of its human resources to operational tasks, and notes that this represents a slight decrease compared to the situation in 2013;
8. 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; notes the publication, in November 2014, of the Agency's revised policy on the handling of declarations of interests by scientific committee members and experts, and welcomes that the revisions reflect a more balanced approach to handling declarations of interests, and aim to effectively restrict the involvement of experts with possible conflicts of interests in the Agency's work, while maintaining the Agency's ability to access the best available expertise; stresses that the Agency should ensure maximum transparency in providing access to clinical reports, and welcomes the Agency's decision to proactively publish data on clinical trials;
9. Notes with concern that, despite the Agency's fee regulation² providing due dates for the collection of fees from applicants and the Agency's related payments to national competent authorities, these due dates were not respected for most of the transactions audited by the Court of Auditors and calls on the Agency to respect those dates;
10. Notes that the Court of Auditors pointed out that in 2014, following an administrative procedure carried out by the Agency, significant weaknesses in management control were reported, implying considerable operational and financial risks to the Agency; acknowledges that an action plan to address the issue was established and implemented, and calls the Agency to thoroughly assess the effectiveness of the measures taken;
11. Notes that in 2014 the Agency concluded a EUR 15 million framework contract (covering the years 2014 to 2017) for high-level management consultancy services; regrets that the objectives and activities to be carried out were not sufficiently specific to justify the procurement decision or the volume of the contract, and that there is no evidence that the Management Board had been consulted on the procurement decision, which would have been appropriate given the nature and value of the contract, even though the Financial Regulation does not require it;
12. Welcomes the Agency's annual environmental reporting;
13. Welcomes the development and adoption by the Agency, in 2014, of an anti-fraud strategy;

² Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 035, 15.2.1995, p.1).

14. Welcomes that the Court of Auditors announced that the transactions underlying the annual accounts of the Agency for the financial year 2014 were legal and regular in all material respects;
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 2014.

RESULT OF FINAL VOTE IN COMMITTEE ASKED FOR OPINION

Date adopted	21.1.2016
Result of final vote	+: 49 -: 10 0: 9
Members present for the final vote	Marco Affronte, Pilar Ayuso, Zoltán Balczó, Catherine Bearder, Ivo Belet, Simona Bonafè, Soledad Cabezón Ruiz, Nessa Childers, Birgit Collin-Langen, Mireille D'Ornano, Miriam Dalli, Seb Dance, Angélique Delahaye, Jörn Dohrmann, Ian Duncan, Stefan Eck, Bas Eickhout, Eleonora Evi, José Inácio Faria, Francesc Gambús, Elisabetta Gardini, Jens Gieseke, Julie Girling, Sylvie Goddyn, Matthias Groote, Françoise Grossetête, Jytte Guteland, György Hölvényi, Anneli Jäätteenmäki, Jean-François Jalkh, Benedek Jávor, Karin Kadenbach, Peter Liese, Norbert Lins, Valentinas Mazuronis, Susanne Melior, Miroslav Mikolášik, Piernicola Pedicini, Bolesław G. Piecha, Marcus Pretzell, Frédérique Ries, Daciana Octavia Sârbu, Annie Schreijer-Pierik, Davor Škrlec, Renate Sommer, Tibor Szanyi, Claudiu Ciprian Tăbărescu, Estefanía Torres Martínez, Nils Torvalds, Glenis Willmott, Damiano Zoffoli
Substitutes present for the final vote	Paul Brannen, Herbert Dorfmann, Christofer Fjellner, Luke Ming Flanagan, Elena Gentile, Martin Häusling, Karol Karski, Andrey Kovatchev, Merja Kyllönen, Marijana Petir, Christel Schaldemose, Jasenko Selimovic, Bart Staes, Mihai Stănescu, Tom Vandenkendelaere, Carlos Zorrinho
Substitutes under Rule 200(2) present for the final vote	Daniel Dalton