



2019/2073(DEC)

11.11.2019

DRAFT 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 2018
(2019/2073(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. Notes that the final budget of the European Medicines Agency ('the Agency') for the financial year 2018 was EUR 337 761 000, representing an increase of 2 % compared to 2017;
2. Recalls that the Agency is a fee-funded agency, with 89,69 % of its 2018 revenue stemming from fees paid by the pharmaceutical industry, 10,28 % stemming from the Union budget and 0,03 % stemming from external assigned revenue;
3. Notes that 581 posts (out of 591 authorised posts in 2018) were occupied on 31 December 2018 (compared to 583 posts out of 596 in 2017);
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. Stresses that a number of the Agency's activities were scaled back, delayed or postponed due to Brexit or other external circumstances; notes with concern that the Agency pointed to a lack of adequate resources for facing a workload that is increasing due to new tasks and legislation, and specifically to the loss of short term contract staff due to relocation and specifics of labour legislation in the Netherlands;
6. Highlights the fact that in 2018, the Agency recommended 94 new medicines for marketing authorisation (84 for human use and 10 for veterinary use), and that those included 46 new active substances (42 for human use and 4 for veterinary use);
7. Notes that in 2018 the second and third phases of the business continuity plan were implemented, in order to safeguard the core activities of the Agency;
8. Is concerned about the delays observed in the development of the EU clinical trials portal and database;
9. Points out that the Agency's data centre was successfully moved to Hamburg in 2018;
10. Takes note that the Agency recorded no internal whistleblower cases and received 21 reports from an external source in 2018, 17 of which were still ongoing on 31 December 2018;
11. Notes with satisfaction that the Agency cooperates with other agencies, notably with the European Centre for Disease Prevention and Control and the European Food Safety Authority (EFSA) in the area of antimicrobial resistance, or with the European Chemicals Agency and EFSA in the area of Innovative 3Rs (replacement, reduction and refinement of animal testing) approaches;
12. Welcomes the fact that the Court of Auditors has stated that it has obtained reasonable assurances that the Agency's annual accounts for 2018 are reliable and that the

underlying transactions are legal and regular;

13. 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 Agency's budget for the financial year 2018.