European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

11.12.2019

2019/2073(DEC)

AMENDMENTS
1 - 7

Draft opinion
Pascal Canfin
(PE641.162v01-00)

2018 discharge: European Medicines Agency (EMA)
(2019/2073(DEC))
Amendment 1
Jutta Paulus

Draft opinion
Paragraph 2

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; and stresses its concerns that the high reliance on direct fees from industry may compromise the public perception of the Agency’s independence;

Amendment

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; and stresses its concerns that the high reliance on direct fees from industry may compromise the public perception of the Agency’s independence;

Or. en

Amendment 2
Anna Zalewska

Draft opinion
Paragraph 5

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;

Amendment

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; calls on all the relevant authorities, including the Dutch authorities, to take action to ensure that the agency is moved as quickly and efficiently as possible to its permanent headquarters so that its work and the assessment of medicine safety are not adversely affected;
Amendment 3  
Jutta Paulus  
Draft opinion  
Paragraph 5

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; regrets that the implementation of the Agency’s policy on publication of clinical data has been put on hold as part of its business continuity plan, which was put in place to deal with the consequences of Brexit;

Amendment 4  
Jutta Paulus  
Draft opinion  
Paragraph 6

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); notes that in 2018, in the framework of its pharmacovigilance activities, the Agency recommended the immediate
suspension and recall of a medicine for multiple sclerosis due to serious and sometimes fatal immune reactions, and the suspension of several antibiotics;

Or. en

Amendment 5
Stanislav Polčák

Draft opinion
Paragraph 7

Draft opinion

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;

Amendment

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; stresses, in this respect, the need to ensure maximum transparency, expertise and independence in the agency's work;

Or. cs

Amendment 6
Stanislav Polčák

Draft opinion
Paragraph 8

Draft opinion

8. Is concerned about the delays observed in the development of the EU clinical trials portal and database;

Amendment

8. Is concerned about the delays observed in the development of the EU clinical trials portal and database; draws attention, in that connection, to the need to solve the problem of the agency's IT infrastructure, which is under heavy strain;

Or. cs

Amendment 7
8 a. Welcomes that, in February 2018, the General Court upheld, in three landmark judgments, the Agency’s decision to release documents in accordance with Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents; whereas two decisions of the General Court have been appealed by pharmaceutical companies;