



2017/2154(DEC)

13.12.2017

AMENDMENTS

1 - 9

Draft opinion

Adina-Ioana Vălean

2016 discharge: European Medicines Agency (EMA)
(2017/2154(DEC))

Amendment 1
Luke Ming Flanagan

Draft opinion
Paragraph 1 a (new)

Draft opinion

Amendment

1 a. Notes with regret the numerous criticisms of the Agency contained in the European Court of Auditors (ECA) Report on the annual accounts of the European Medicines Agency for the financial year 2016; notes also with regret the Agency's tepid response to those criticisms and recommends that it should be far more receptive of the constructive criticisms and recommendations offered by the Court, and act accordingly to take whatever corrective and preventative measures are necessary;

Or. en

Amendment 2
Mireille D'Ornano

Draft opinion
Paragraph 2

Draft opinion

Amendment

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;

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; ***points out that the share of the Agency's revenue that comes from fees paid by the pharmaceutical industry, which is now very high, should be accompanied by increased requirements regarding the Agency's independence from the pharmaceutical industry;***

Or. fr

Amendment 3
Claudiu Ciprian Tănăsescu

Draft opinion
Paragraph 2 a (new)

Draft opinion

Amendment

2a. Points out that the Agency monitors budget consumption through a robust monitoring process;

Or. ro

Amendment 4
Mireille D'Ornano

Draft opinion
Paragraph 5

Draft opinion

Amendment

5. 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;

5. 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;
nevertheless encourages the Agency to continue this important work of providing information for the general public;

Or. fr

Amendment 5
Mireille D'Ornano

Draft opinion
Paragraph 6

Draft opinion

Amendment

6. 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;

6. 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; *invites this taskforce to work constructively, and to take account of all the positive implications of Brexit for the functioning of the Agency;*

Or. fr

Amendment 6
Claudiu Ciprian Tănăsescu

Draft opinion
Paragraph 6 a (new)

Draft opinion

Amendment

6a. Notes that setting up a fully transparent reporting system is costly and complicated, owing to the complexity of the system and the significant number of transactions processed every year;

Or. ro

Amendment 7
Karin Kadenbach

Draft opinion
Paragraph 7 a (new)

Draft opinion

Amendment

7 a. 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 in Amsterdam, 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;

Or. en

Amendment 8
Mireille D'Ornano

Draft opinion
Paragraph 9

Draft opinion

9. 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 the expert's 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;

Amendment

9. 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 the expert's 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;
nevertheless encourages the Agency further to strengthen its internal policy on combating conflicts of interest and its independence from the pharmaceutical industry;

Or. fr

Amendment 9
Claudiu Ciprian Tănăsescu

Draft opinion

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Paragraph 11 a (new)

Draft opinion

Amendment

11a. Notes that the Agency has been facing a significant risk of instability, owing to the unsuccessful process of reallocating key staff in the area of IT and administration;

Or. ro