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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 2016
(2017/2154(DEC))

Rapporteur:Adina-Ioana Vălean

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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. 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. 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;

4. 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;

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;

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;

7. Stresses that the Agency was not allowed to create a 'Brexit' contingency reserve;

8. 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;

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;

10. 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;

11. Notes the Agency achieved occupancy rate of 98 % for temporary agents;

12. 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.