European Parliament
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Plenary sitting

A8-0103/2018

26.3.2018

REPORT

on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2016
(2017/2154(DEC))

Committee on Budgetary Control

Rapporteur: Bart Staes

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1. PROPOSAL FOR A EUROPEAN PARLIAMENT DECISION

on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2016
(2017/2154(DEC))

The European Parliament,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2016,

– having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2016, together with the Agency's reply[1],

– having regard to the statement of assurance[2] as to the reliability of the accounts and the legality and regularity of the underlying transactions provided by the Court of Auditors for the financial year 2016, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of 20 February 2018 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2016 (05941/2018 – C8-0064/2018),

– having regard to Article 319 of the Treaty on the Functioning of the European Union,

– having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002[3], and in particular Article 208 thereof,

– having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[4], and in particular Article 68 thereof,

– having regard to Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council[5], and in particular Article 108 thereof,

– having regard to Rule 94 of and Annex IV to its Rules of Procedure,

– having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on the Environment, Public Health and Food Safety (A8-0103/2018),

[1] OJ C 417, 6.12.2017, p. 142.
[2] OJ C 417, 6.12.2017, p. 142.
[3] OJ L 298, 26.10.2012, p. 1.
[4] OJ L 136, 30.4.2004, p. 1.
[5] OJ L 328, 7.12.2013, p. 42.

1. Grants the Executive Director of the European Medicines Agency discharge in respect of the implementation of the Agency's budget for the financial year 2016;

2. Sets out its observations in the resolution below;

3. Instructs its President to forward this decision, and the resolution forming an integral part of it, to the Executive Director of the European Medicines Agency, the Council, the Commission and the Court of Auditors, and to arrange for their publication in the *Official Journal of the European Union* (L series).

2. PROPOSAL FOR A EUROPEAN PARLIAMENT DECISION

on the closure of the accounts of the European Medicines Agency for the financial year 2016
(2017/2154(DEC))

The European Parliament,

– having regard to the final annual accounts of the European Medicines Agency for the financial year 2016,

– having regard to the Court of Auditors' report on the annual accounts of the European Medicines Agency for the financial year 2016, together with the Agency's reply[1],

– having regard to the statement of assurance[2] as to the reliability of the accounts and the legality and regularity of the underlying transactions provided by the Court of Auditors for the financial year 2016, pursuant to Article 287 of the Treaty on the Functioning of the European Union,

– having regard to the Council's recommendation of 20 February 2018 on discharge to be given to the Agency in respect of the implementation of the budget for the financial year 2016 (05941/2018 – C8-0064/2018),

– having regard to Article 319 of the Treaty on the Functioning of the European Union,

– having regard to Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002[3], and in particular Article 208 thereof,

– having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[4], and in particular Article 68 thereof,

– having regard to Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council[5], and in particular Article 108 thereof,

– having regard to Rule 94 of and Annex IV to its Rules of Procedure,

– having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on the Environment, Public Health and Food Safety (A8-0103/2018),

[1] OJ C 417, 6.12.2017, p. 142.
[2] OJ C 417, .6.12.2017, p. 142.
[3] OJ L 298, 26.10.2012, p. 1.
[4] OJ L 136, 30.4.2004, p. 1.
[5] OJ L 328, 7.12.2013, p. 42.

1. Approves the closure of the accounts of the European Medicines Agency for the financial year 2016;

2. Instructs its President to forward this decision to the Executive Director of the European Medicines Agency, the Council, the Commission and the Court of Auditors, and to arrange for its publication in the *Official Journal of the European Union* (L series).

3. MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2016
(2017/2154(DEC))

The European Parliament,

– having regard to its decision on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2016,

– having regard to Rule 94 of and Annex IV to its Rules of Procedure,

– having regard to the report of the Committee on Budgetary Control and the opinion of the Committee on the Environment, Public Health and Food Safety (A8-0103/2018),

A. whereas in the context of the discharge procedure, the discharge authority wishes to stress the particular importance of further strengthening the democratic legitimacy of the Union institutions by improving transparency and accountability and implementing the concept of performance-based budgeting and good governance of human resources;

B. whereas, according to its statement of revenue and expenditure[1], the final budget of the European Medicines Agency ("the Agency") for the financial year 2016 was EUR 308 422 000, representing an increase of 0,1 % compared to 2015;

C. whereas the Agency is a fee-funded agency, with 89,34% of its 2016 revenue stemming from fees paid by the pharmaceutical industry, for services provided, 5,49% stemming from the Union budget to fund various public health and harmonisation activities, and 5,01% stemming from external assigned revenue;

D. whereas the Court of Auditors ("the Court") in its report on the annual accounts of the European Medicines Agency for the financial year 2016 ("the Court's report"), has stated that it has obtained reasonable assurances that the Agency's annual accounts are reliable and that the underlying transactions are legal and regular;

Follow-up of 2014 discharge

1. Notes with concern that some of the Court's comments from the 2014 discharge are still not marked as "completed", in particular the evaluation of the weaknesses in management control, the dissemination of appropriate pharmacovigilance information to the Member States and to the general public; calls on the Agency to complete the corrective actions as soon as possible in 2018 and to report to the discharge authority on their implementation;

Comments on the reliability of the accounts

2. Notes that, according to the Court's report, since the introduction of a new IT accounting system in 2011, reporting on commitment workflow and consumption has

[1] OJ C 443, 29.11.2016, p.4

not been sufficiently transparent; notes with regret that, although the matter was repeatedly raised with the Agency, no corrective action has been taken; take note of the Agency's explanation that "[the Agency] is currently working to increase the reporting functionality of its financial system, in line with the recommendations by the Court"; calls on the Agency to implement corrective actions as soon as possible in 2018 and to report to the discharge authority on their implementation;

Comments on the legality and regularity of transactions

3. Notes with concern that, according to the Court's report, the Agency concluded corporate rate agreements for the provision of accommodation for experts with 25 hotels in London without using a competitive procurement procedure; notes that for six hotels, payments made in 2016 were above the Financial Regulation's threshold for which an open or restricted competitive procurement procedure is required; notes with regret that the six corporate rate agreements and the related 2016 payments, amounting to some EUR 2 100 000 are therefore irregular; notes that, according to the Agency's reply, it will identify and implement a solution for hotel bookings during 2017-2018; calls on the Agency to report to the discharge authority on the implementation of that solution;

Budget and financial management

4. Notes that budget monitoring efforts during the financial year 2016 resulted in a budget implementation rate of 96,30 %, representing an increase of 2,25 % compared with the previous year; notes furthermore that the payment appropriations execution rate was at 85,51 %, representing a decrease of 1,58 %;

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

Commitments and carry-overs

6. Notes that no specific comments were issued by the Court as regards the Agency's carry-overs; notes in addition that the Agency fully complied with relevant financial rules and key performance indicators for the amounts carried over, resulting in carry-overs for Title I at 0,86 %, for Title II at 7,93 % and for Title III at 25,86 %;

7. Points out that carry-overs are often partly or fully justified by the multiannual nature of the agencies' operational programmes, do not necessarily indicate weaknesses in budget planning and implementation, and are not always at odds with the budgetary principle of annuality, in particular if they are planned in advance and communicated to the Court;

Transfers

8. Notes with satisfaction that, according to the Agency's annual activity report, the level and nature of transfers in 2016 remained within the limits of the financial rules; acknowledges from the Agency that during 2016 it made twelve transfers totalling EUR 9 268 000 or 3% of final appropriations; notes that the transferred expenditure appropriations were primarily needed to cover increased expenditure on business IT development, increased appropriations for rapporteurs and pharmacovigilance services,

and reduction of appropriations, where expenditure is mainly paid in pounds sterling;

Procurement and staff policy

9. Observes from the Agency's establishment plan that 587 posts (out of 602 posts authorised under the Union budget) were occupied on 31 December 2016, as it was in 2015; notes that in addition the Agency was employing (in FTEs) 36 seconded national experts, 143 contract staff, 59 interim staff and 148 consultants;

10. Notes with regret that, as regards the number of posts occupied on 31 December 2016 for all staff (including contract agents), gender balance has not been met, since the ratio is 69 % female to 31 % male; notes however that 14 out of 29 (48%) of the Agency's senior management staff are female; calls on the Agency to take the gender balance issue into account when recruiting new staff and inform the discharge authority in the next discharge procedure of the progress made at the end of the calendar years of 2017 and 2018;

11. Notes that on average the Agency's staff was on sick leave 7,9 days in 2016; observes with satisfaction that the Agency put in place a health & safety group for consultation with staff, provides its staff with healthy food options in the Agency canteen and made an annual contribution of £ 31 108,33 to the Sports and Leisure Club that arranges activities such as a summer party and a Christmas party, and also has nine sport and leisure activity clubs within the areas of art, books, cinema, theatre, basketball, football, mountain sports, Nordic walking and volleyball;

12. Notes with satisfaction that the Agency has a policy in place for protecting the dignity of the person and preventing any form of psychological or sexual harassment; notes that the Agency also has listening points (confidential counsellors) in place for staff to bring their concerns within the informal procedure; notes that there were no harassment cases in 2016;

13. Notes that the Agency does not have any official vehicles;

14. Notes that the result of the staff engagement survey, carried out in 2015, represented a further improvement compared to 2013; observes, however, that remaining issues identified include collaboration across divisions, objectivity in decision-making processes and trust in senior management; notes that a focus group proposed eight improvement actions for the three areas of improvement; acknowledges that six of the proposals were endorsed by the Executive Board, out of which three are already in the implementation phase (internal mobility database; fact sheets for communication of decisions; regular team meetings), and three more are planned to follow (360 degree feedback process; personnel communication plan; better support for line managers); calls on the Agency to report to the discharge authority on the implementation of these actions;

15. Notes that, according to the Court's report, since 2014 the Agency has undergone two major re-organisations including the internal re-allocation of top and middle management positions; notes moreover that the re-allocation of key staff in the area of IT and administration was not successful, causing material risk of instability to the Agency and its operations; notes however that the Agency considers that no instability

was suffered by the Agency due to organisational changes which aimed at increasing operational efficiencies and improving delivery of strategic objectives and which were supported by the Agency's Management Board; notes moreover that there is no system in place to analyse skills availability, identify gaps and to recruit and allocate appropriate staff; calls on the Agency to pay extra attention to these issues, improve its human resources management and report back to the discharge authority;

16. 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, 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;

17. Notes that, according to the Court's report, the Agency is critically dependent on external expertise from the start of the projects, yet there is no policy in place to govern the use of consultants; notes with regret that quality issues identified upon receipt of deliverables required rectification for which additional costs were charged to the Agency; calls on the Agency to better use its own resources and try to limit dependency on external expertise, to prepare and set up a proper policy to govern the use of external consultants and to report to the discharge authority on its implementation;

18. Notes that, according to the Court's report, in 2014 the Commission, on behalf of more than 50 Union institutions and bodies (including the Agency), signed a framework contract with one contractor for the acquisition of software, licences and the provision of related IT maintenance and consultancy; notes that the framework contractor acts as an intermediary between the Agency and suppliers that can address the Agency's needs; takes note that for these intermediary services, the framework contractor is entitled to a commission of two to nine percent of the suppliers' prices; observes that in 2016, total payments to the framework contractor amounted to EUR 8 900 000; notes with regret that the Agency did not systematically check prices and uplifts charged with the suppliers' quotes and invoices issued to the framework contractor; notes however that, following the Court's finding in October 2017, the Agency investigated the case which resulted in the contractor's acknowledgment of its mistake and an expected recovery of approximately EUR 12 000; also notes that, since October 2017, specific internal guidance has been put in place by the Agency; that guidance includes systematic checks of product category and related uplift for every quotation received from Comparex with a value above EUR 60 000;

19. Acknowledges that approvals of marketing authorisation applications are based on three criteria: efficacy, quality and safety; recommends that a fourth requirement should be added: Added Therapeutic Value (ATV), comparing a medicine with the best available drug, instead of comparing it to placebos;

Prevention and management of conflicts of interests, transparency and democracy

20. Notes that the revised policy on the handling of competing interests of the Management Board members came into effect on 1 May 2016 and was further revised in October 2016; acknowledges from the Agency that the implementation of the revised policy now includes an ex ante evaluation which is performed to compare the details contained in each new declaration, with those of the previous declaration, and with the CV of each board member provided;

21. Welcomes the fact that the names of members who have declared competing interests which could affect their impartiality, with regard to specific items on the agenda, are noted in the minutes and that that may imply some restriction on their involvement at the meeting;

22. Notes with satisfaction that the CVs and declarations of interests of all Management Board members are published on the Agency's website; notes that no breach of trust procedures were initiated for Management Board members in 2016;

23. Observes that the Agency's Code of Conduct extends the requirements for impartiality and the submission of annual declarations of interests to all members of staff of the Agency, including temporary agents, contract agents, seconded national experts, interims, visiting experts and trainees; notes that the decision concerning the handling of declared interests of members of staff of the Agency and candidates before recruitment was revised as a result of the review of both the policy on the handling of declarations of interests of scientific committee members and experts, and the policy on competing interests of the Management Board members, and became effective as of 1 January 2017;

24. Notes that the relocation of the Agency could lead to staff leaving the Agency; calls therefore on the Agency to make sure that revolving door rules are strictly applied in each case;

25. Notes that the Agency's anti-fraud office delivered on the targeted actions, outlined in the Agency’s anti-fraud strategy for 2016; all staff were requested to attend the Agency’s e-learning course covering anti-fraud related matters and entirely prepared in-house by the anti-fraud office;

26. Takes note that the Agency has adopted the Commission guidelines on internal whistleblowing in November 2014; welcomes the adoption by the Agency‘s Management Board of a policy to handle external sources’ reports on matters within the scope of its responsibilities (i.e. external whistleblowing rules) in March 2017;

27. Acknowledges from the Agency that in 2016, it recorded no internal whistleblower cases and received 18 reports from an external source concerning alleged improprieties of a regulatory nature, potentially adversely affecting public health; notes that the Agency followed-up on each of these reports but did not identify any safety/efficacy concerns entailing the need to take specific regulatory action;

28. Expresses the need to establish an independent disclosure, advice and referral body with sufficient budgetary resources, in order to help whistleblowers use the right channels to

disclose their information on possible irregularities affecting the financial interests of the Union, while protecting their confidentiality and offering needed support and advice;

29. Notes that in 2016 the Agency received 823 requests for access to documents which represent a 20 % increase compared to 2015; notes that the Agency replied to 678 requests and granted full access to 542 requests, 17 requests were granted only partial access and 44 requests were refused; notes that the reason given by the Agency for refusing 21 requests for access to documents was the protection of commercial interests; calls on the Agency to ensure that, when deciding on limiting the access to documents due to protection of commercial interests, it also considers the Union and its citizens' interest in health with seriousness, while applying relevant rules and regulations;

30. Notes with regret 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;

Main achievements

31. Welcomes the main achievements identified by the Agency in 2016, namely:

– the Agency fulfilled its legal obligations of supporting innovation, authorisation and supervision of medicinal products, thus promoting and protecting public health;

– the Agency started publishing clinical data underpinning marketing authorisation applications for new medicines, and was the first regulator in the world to do so;

– the Agency launched PRIority MEdicines (PRIME), a new scheme to reinforce regulatory support to optimise the development of medicines that address patients' unmet needs;

– together with the European Food Safety Authority, the Agency reviewed the measures to reduce the use of antimicrobials in food-producing animals and delivered a joint scientific opinion;

Internal controls

32. Takes note that the Agency has developed a sustainable process to identify, assess, and manage risks across the organisation, to ensure attainment of key organisational objectives; notes that none of the identified risks were considered critical and none had materialised during 2016;

33. Notes that the effectiveness of the Agency's Internal Control Standards was assessed via an internal questionnaire addressed to the Agency's management; acknowledges that the assessment concluded that the system in place is generally compliant with the standards, thus providing the Agency with reasonable assurance on the reliability of the internal control environment, even though three areas for improvement were highlighted; namely, staff allocation and mobility, objectives, and performance indicators and operational structure; notes that measures have been taken to further

improve the efficiency and application of the standards above, and an action plan to rectify the above areas was drafted and it was to be implemented in 2017; calls on the Agency to report to the discharge authority on the implementation of the action plan;

Internal audit

34. Notes that 10 recommendations marked as “Very Important” and stemming from audits carried out by the Agency’s Internal Audit Capability up to 31 December 2015, were still open at the end of 2016; notes that no critical recommendations remain open; calls on the Agency to report to the discharge authority on the measures taken to complete the open recommendations marked as “Very Important”;

35. Notes with satisfaction that no recommendations marked as “Critical” or “Very Important” from the Commission’s Internal Audit Service were open as of 31 December 2016;

Other Comments

36. Notes in particular that the Agency will be facing an additional workload and additional budgetary needs throughout the 2018-2020 relocation and transition period, as a consequence of the decision of the United Kingdom (UK) to withdraw from the Union; calls on the Commission to make available adequate staff and budgetary resources during this period to ensure that the Agency can both continue to carry out its tasks effectively and launch all required activities in preparation for its relocation in 2019; proposes in addition that the Agency, limited by legislation and in line with the principle of sound financial management, be authorised to maintain a budgetary reserve generated from revenue fees to respond to unforeseen costs and unfavourable exchange rate fluctuations that may be incurred in 2018 and beyond;

37. Stresses the need for the accelerated building approval procedure set out in Article 88 of the Agency’s framework financial regulation so as to avoid any delays in the start of the construction of the new Agency’s premises in Amsterdam;

38. Welcomes the Parliament's mission to Amsterdam, at the temporary and future headquarters of the Agency, to gather up-to-date information on the progress of the double transfer and on the development of the real estate project and underlines the role of the Parliament in the decision-making process regarding the new headquarters;

39. In the context of the Agency’s impending relocation to Amsterdam and the need to secure the highest possible retention of staff, supports a broad interpretation of point (a) of Article 12(2) of the Conditions of Employment of Other Servants of the Union, thus enabling the Executive Director to retain the highest possible number of the Agency’s staff members of UK nationality until 29 March 2019 and beyond;

40. Notes that the Court issued an emphasis of matter paragraph for the two London-based agencies, concerning the UK’s decision to withdraw from the Union; notes that in view of the decisions on its future location, the Agency has disclosed in its financial statements an estimated EUR 448 000 000 rent for the remaining rental period between 2017 and 2039 as a contingent liability, as the rental contract does not include any exit clause; urges the Commission to take responsibility for these absurdly high liabilities

and, together with the Agency, negotiate an acceptable deal with the lessor; notes moreover that contingent liabilities in relation to other costs associated with the removal such as, for example the relocation of staff together with their families, actions to mitigate a potential loss of internal and UK-based external expertise, and the consequent risk to business continuity, are yet to be determined; calls on the Agency to report to the discharge authority on an updated estimate of relocation costs, which includes liability of the current premises;

41. Points out from the Court's report that the Agency's 2016 budget was 95 % financed by fees from pharmaceutical companies and 5 % from Union funds; stresses that the funding from pharmaceutical companies has increased in 2016, compared to 2015 and is concerned about the influence of the industry on the Agency and also about this dependence;

42. Notes that the assessment of risks related to 'Brexit' has been performed separately by the Operations and Relocation Preparedness Task Force (ORP taskforce) of the Agency, set up to ensure the Agency's preparedness for various development scenarios following Brexit; notes that in 2016, the taskforce was focused on the assessment of the impact on the Agency, including managing preparations related to support for staff and delegates, financial matters, security issues and infrastructure, concerning the planned relocation to another country; calls on the Agency to report to the discharge authority on the measures taken to face this challenge;

43. Acknowledges from the follow-up report that the ORP Task Force has officially stated that all costs for the early departure from London and relocation of the Agency to the new host Member State will have to be borne by the UK Government; acknowledges moreover that, in the meantime, as a tenant, the Agency is analysing all possible options with the assistance of UK-based legal and real estate advisors, whilst keeping an eye on the negotiations between the Union and the UK Government;

44. Notes that, according to the Court's report, Regulation (EC) No 726/2004 requires an external evaluation of the Agency and its operations by the Commission every ten years; observes that the last evaluation report was issued in 2010; agrees with the Court's comment that such a long time span does not ensure timely performance feedback for stakeholders; acknowledges from the Agency that the Commission is currently preparing the next evaluation to be conducted in the period 2017-2018;

45. 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;

46. 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;

47. 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;

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48. Refers, for other observations of a cross-cutting nature accompanying its decision on discharge, to its resolution of xx April 2018[1] on the performance, financial management and control of the agencies.

[1] Texts adopted of that date, P8_TA-PROV(2018)0000.

25.1.2018

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

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

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. 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;

6. 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;

7. 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;

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

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

10. 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, 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;

11. 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;

12. 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 experts’ 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;

13. 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;

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

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 2016.

INFORMATION ON ADOPTION IN COMMITTEE ASKED FOR OPINION

Date adopted	24.1.2018
Result of final vote	+: 41 –: 8 0: 0
Members present for the final vote	Marco Affronte, Pilar Ayuso, Ivo Belet, Simona Bonafè, Biljana Borzan, Paul Brannen, Soledad Cabezón Ruiz, Nessa Childers, Birgit Collin-Langen, Seb Dance, Stefan Eck, José Inácio Faria, Francesc Gambús, Elisabetta Gardini, Gerben-Jan Gerbrandy, Arne Gericke, Julie Girling, Françoise Grossetête, Andrzej Grzyb, Jytte Guteland, Anneli Jäätteenmäki, Karin Kadenbach, Urszula Krupa, Giovanni La Via, Peter Liese, Susanne Melior, Gilles Pargneaux, Piernicola Pedicini, Bolesław G. Piecha, John Procter, Julia Reid, Frédérique Ries, Daciana Octavia Sârbu, Renate Sommer, Claudiu Ciprian Tănăsescu, Ivica Tolić, Adina-Ioana Vălean, Jadwiga Wiśniewska, Damiano Zoffoli
Substitutes present for the final vote	Elena Gentile, Martin Häusling, Norbert Lins, Nuno Melo, Ulrike Müller, Christel Schaldemose, Bart Staes, Keith Taylor, Carlos Zorrinho
Substitutes under Rule 200(2) present for the final vote	Jiří Maštálka

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

41	+
ALDE	Gerben-Jan Gerbrandy, Anneli Jäätteenmäki, Ulrike Müller, Frédérique Ries
GUE/NGL	Stefan Eck, Jiří Maštálka
PPE	Pilar Ayuso, Ivo Belet, Birgit Collin-Langen, José Inácio Faria, Francesc Gambús, Elisabetta Gardini, Françoise Grossetête, Andrzej Grzyb, Giovanni La Via, Peter Liese, Norbert Lins, Nuno Melo, Renate Sommer, Ivica Tolić, Adina-Ioana Vălean
S&D	Simona Bonafè, Biljana Borzan, Paul Brannen, Soledad Cabezón Ruiz, Nessa Childers, Seb Dance, Elena Gentile, Jytte Guteland, Karin Kadenbach, Susanne Melior, Gilles Pargneaux, Christel Schaldemose, Daciana Octavia Sârbu, Claudiu Ciprian Tănăsescu, Damiano Zoffoli, Carlos Zorrinho
VERTS/ALE	Marco Affronte, Martin Häusling, Bart Staes, Keith Taylor

8	-
ECR	Arne Gericke, Julie Girling, Urszula Krupa, Bolesław G. Piecha, John Procter, Jadwiga Wiśniewska
EFDD	Piernicola Pedicini, Julia Reid

0	0

Key to symbols:
+ : in favour
- : against
0 : abstention

INFORMATION ON ADOPTION IN COMMITTEE RESPONSIBLE

Date adopted	20.3.2018
Result of final vote	+: 19 –: 5 0: 0
Members present for the final vote	Nedzhmi Ali, Inés Ayala Sender, Zigmantas Balčytis, Dennis de Jong, Tamás Deutsch, Martina Dlabajová, Raffaele Fitto, Ingeborg Gräßle, Cătălin Sorin Ivan, Jean-François Jalkh, Arndt Kohn, Notis Marias, José Ignacio Salafranca Sánchez-Neyra, Petri Sarvamaa, Claudia Schmidt, Bart Staes, Indrek Tarand, Marco Valli, Derek Vaughan, Tomáš Zdechovský, Joachim Zeller
Substitutes present for the final vote	Karin Kadenbach, Julia Pitera, Miroslav Poche

FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

19	+
ALDE	Nedzhmi Ali, Martina Dlabajová
PPE	Tamás Deutsch, Ingeborg Gräßle, Julia Pitera, José Ignacio Salafranca Sánchez-Neyra, Petri Sarvamaa, Claudia Schmidt, Tomáš Zdechovský, Joachim Zeller
S&D	Inés Ayala Sender, Zigmantas Balčytis, Cătălin Sorin Ivan, Karin Kadenbach, Arndt Kohn, Miroslav Poche, Derek Vaughan
VERTS/ALE	Bart Staes, Indrek Tarand

5	-
ECR	Raffaele Fitto, Notis Marias
EFDD	Marco Valli
ENF	Jean-François Jalkh
GUE/NGL	Dennis de Jong

0	0

Key to symbols:
+ : in favour
- : against
0 : abstention