2015 discharge: European Medicines Agency (EMA)

2016/2169(DEC) - 27/04/2017 - Text adopted by Parliament, single reading

The European Parliament decided to **grant discharge** to the Executive Director of the European Medicines Agency (EMA) in respect of the implementation of the budget of Agency for the financial year 2015.

The vote on the decision on discharge covers the closure of the accounts (in accordance with Annex IV, Article 5 (1) (a) to Parliament's Rules of Procedure).

Noting that the Court of Auditors has stated that it has obtained reasonable assurances that the Agency's annual accounts for the financial year 2015 are reliable and that the underlying transactions are legal and regular, Parliament adopted by 510 votes to 101 with 13 abstentions, a resolution containing a series of recommendations, which form an integral part of the decision on discharge and which add to the general recommendations set out in the resolution on performance, financial management and control of EU agencies.

These recommendations may be summarised as follows:

- **Agency's financial statements**: Parliament noted the final budget of the European Medicines Agency for the financial year 2015 was EUR 308 097 000 representing an increase of 9.07 % compared to 2014.
- **Prevention and management of conflicts of interests and transparency**: It acknowledged that the revised policy on the handling of declarations of interests of scientific committees' members and experts entered into force in 2015. Parliament also made a series of observations regarding the budgetary and financial management, commitments and carry-overs, transfers, procurement and recruitment procedures, the prevention and management of conflicts of interests and internal audits and controls.

Communication: Parliament noted that in 2015, the **Agency recommended 93 medicines for marketing authorisation** and that those include 39 new active substances. It stressed 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.

Parliament reminded the Agency that Directive 2003/63/EC states that medicines can only be considered for Union marketing authorisation if they have been tested in accordance with ethical guidelines, and reminded the Agency of its commitment to perform extra checks on clinical trials carried out outside the European Union before granting a drug market authorisation. Therefore, due to the special vulnerabilities of those tests, Parliament asked the Agency to report to the discharge authority every year on actions taken to ensure drugs for the Union market were **tested ethically in lower and middle income countries**, in accordance with the law.

It underlined that the Agency should continue promoting dialogue with stakeholders and citizens and incorporate it as part of the priorities and activities to be implemented.

Adaptive pathways: Parliament noted that the Agency launched a pilot project on "adaptive pathways" in March 2014 aiming to accelerate market authorisations for specific medicines using the so-called post-marketing authorisation. It is concerned that the pilot project raises numerous public health concerns and

undermines the core mission of the Agency, namely to ensure safety of medicines. It asked the Agency to report to the discharge authority on the project and the measures it has taken to ensure that this acceleration of the procedure does not undermine its core mission.

Impact of Brexit: Parliament stated that on 23 June 2016, the citizens of the United Kingdom voted to leave the European Union. It noted that following the outcome of the UK referendum on 23 June 2016, the Agency established a dedicated task force to focus on **relocation** preparedness, operational and financial preparedness, HR-related matters and communication (internal and external) aspects. It observed that the work currently ongoing is focussed on the impact of a loss of EMA staff in the event of relocation and loss of external expertise due to the potential unavailability of UK expertise in the scientific committees and other EMA fora. An impact assessment including remedial solutions should be available by the end of the first quarter of 2017.

Lastly, Parliament noted with concern that the Agency's rental contract until 2039 does **not include an early termination clause to release the Agency** from the liabilities of rent and associated costs, and that the payable rent for the remaining period from 2017 to 2039 is estimated at EUR 347.6 million. It asked the Agency to report to the discharge authority on any developments on this matter.