2021 discharge: European Medicines Agency (EMA)

2022/2109(DEC) - 10/05/2023 - Text adopted by Parliament, single reading

The European Parliament decided to **grant discharge** to the Executive Director of the European Medicines Agency (EMA) for the financial year 2021 and to approve the closure of the accounts for that year.

Noting that the Court of Auditors has stated that it has obtained reasonable assurance that the Agency's annual accounts for the financial year 2021 are reliable and that the underlying transactions are legal and regular, Parliament adopted, by 548 votes to 73 with 5 abstentions, a resolution containing a series of recommendations which form an integral part of the discharge decision and which complement the general recommendations set out in the resolution on the performance, financial management and control of EU agencies.

Agency's financial statements

The Agency's final budget for the year 2019 was EUR 379 228 000, representing an increase of 2.56 % compared to 2020. The Agency is a fee-funded agency, with approximately 89.40 % of its 2021 revenue stemming from fees paid by the pharmaceutical industry for services provided, 9.90 % stemming from the Union budget and 0.7 % stemming from external assigned revenue.

Budgetary and financial management

Budget monitoring efforts during the financial year 2021 resulted in a budget implementation rate of current year commitment appropriations of 96.38 %, representing a decrease of 2.46 % compared to 2020. Payment appropriations execution rate was 72.36 %, representing a decrease of 6.11 % compared to 2020.

Other observations

Parliament also made a series of observations concerning performance, staff, conflicts of interest, internal controls and digitalisation.

In particular, it noted that:

- despite the difficulties caused by the COVID-19 pandemic, the Agency continued to promote a functioning single market for human and veterinary medicines, by acting as the hub of the European network of regulatory medicines authorities that implements the applicable Union legislative framework for such products;

- the Agency recommended for approval, 92 new human medicines and 12 new veterinary medicines recommended for marketing authorisation, six PRIME-designated medicines recommended for approval and 19 orphan-status designations confirmed;

- the targets of most of the Agency's workload and key performance indicators were achieved or exceeded, while the achievement of most of the objectives set was on track or completed;

- the Agency further strengthened its cybersecurity capabilities and defence;

- on 31 December 2021, the establishment plan was 98.02 % implemented, with 644 temporary agents appointed out of 657 temporary agents authorised under the Union budget (compared to 596 authorised posts in 2020);

- the addition of new tasks and the increasing fee-related workload due to the growing portfolio of authorised medicines over the years was not accompanied by an adequate increase in the Agency's staff, which puts the Agency under significant pressure;

- the Agency is urged to explore ways of surveying the staff regarding their well-being and deploying methods that would prevent burn-out and decreased performance;

- 2021 was the third year in a row when the Court raised new procurement-related observations for the Agency;

- potential liabilities arising, until 2039, from the lease on the Agency’s former office premises in London remain an ongoing issue. The estimated amount corresponding to such liabilities has risen from EUR 377 million on 31 December 2020 to EUR 383 million on 31 December 2021;

- no internal whistleblowing case was reported in 2021, however, 29 reports of external whistleblowing cases were received, of which 23 cases were closed and 6 cases are still ongoing;

- systematic rules on transparency, incompatibilities, conflicts of interest, illegal lobbying and revolving doors should be maintained and the Agency should revise and improve its code of conduct and continue strengthening its internal control and audit mechanisms, including the setting up of an internal anti-corruption mechanism;

- a high degree of transparency should be ensured by the Agency given that the majority of funding comes from private sources;

- the Agency is called on to address the weaknesses found by the Court in the area of recruitment and strengthen its internal control system;

- a move to paper-less document management and the speeding up of the digitalisation is highlighted;

- in 2021 the Agency developed a new five-year framework strategy for external communication and engagement, covering 2021 to 2025, that aims to build a better understanding of the Agency and its work among Union citizens, as well as to provide a strategic framework for the development of annual communication and engagement plans.