Fees and charges payable to the European Medicines Agency

2022/0417(COD) - 12/07/2023 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 595 votes to 25, with 25 abstentions, **amendments** to the proposal for a regulation of the European Parliament and of the Council of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council.

The matter was referred back to the committee responsible for inter-institutional negotiations.

Adequate funding

Members pointed out that as a result of the COVID-19 pandemic and the increase in the number of health initiatives at EU level, the Agency is facing an ever-increasing workload, leading to additional budgetary needs in terms of staff and financial resources. In order to preserve the integrity of the Agency and its independence, and to ensure public confidence in the legislative and regulatory framework for pharmaceutical products in the EU, the Agency must have sufficient funding to carry out its obligations and transparency commitments.

Payment of remuneration to competent authorities of the Member States for the provision of services to the Agency

Where the Agency grants a full waiver of fees, the remuneration of rapporteurs and co-rapporteurs appointed by the competent authorities of the Member States should be reduced by 50% or 100%, as set out in Annex V.

Taking account of inflation rates

Inflation was high at the time of the proposal for this Regulation; it remains high in 2023 and is forecast by the European Central Bank to remain high in 2024. The corresponding amounts need to be updated to ensure that royalties, fees and remuneration payable are adjusted to take account of inflation before the date of application of the Regulation.

The Commission should therefore adopt a delegated act to amend the relevant Annexes to this Regulation on the basis of the inflation rate published four months before the date of application of the Regulation.

Reductions of fees and charges

It is proposed that, on a duly justified proposal from the Executive Director of the Agency, in particular for the protection of public or animal health or for the support of specific types of products or types of applicants, selected for duly justified reasons, the Management Board of the Agency may grant, following a favourable opinion from the Commission, a total or partial reduction of the applicable amount. The Agency should make information on such reductions **publicly available** on the Agency’s website, setting out the reasons for the reduction.

Transparency and monitoring

The amounts set out in the Annexes should be published on the website of the Agency and should be updated to reflect any changes.

The Agency should monitor its costs and its Executive Director should provide without delay, in his annual activity report to the European Parliament, the Council, the Commission and the Court of Auditors, detailed and substantiated information on the costs to be covered by the fees and charges covered by the Regulation. This information should include information relating in particular to the practical aspects of carrying out the activities for which the Agency levies fees or charges.

All fees received, including those where reductions and waivers have been granted, and fees which are due but not yet received by the Agency should be **published on the Agency's website** and listed in its annual report. The Agency's annual report should furthermore list a detailed breakdown of all remunerated amounts paid to national authorities for their work.

Revision

The amended text stated that the Commission may take into account other factors that could have a substantive impact on the Agency's budget, including but not limited to its workload and potential risks related to fluctuations in its fee revenues. The level of fees should be set at a level which ensures that the revenue derived from them, when combined with other sources of revenue of the Agency, is sufficient to cover the costs of the services delivered in accordance with the key performance indicators and transparency principles.

Annexes

The amended text revises the Annexes regarding fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use and veterinary medicinal products. Members proposed that a total reduction to the fee for protocol assistance and scientific advice requests on medicinal products should be granted to **applicants from academia or the academic sector**. They also requested that a fee reduction of **30%** (instead of 20%) be applied to the annual pharmacovigilance fee.