Fees and charges payable to the European Medicines Agency

2022/0417(COD) - 30/06/2023 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Cristian-Silviu BUOI (EPP, RO) on 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 committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

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.

Monitoring inflation rates

The Commission should monitor the inflation rate, in relation to the amounts of fees, charges and remuneration set out in the Annexes to this Regulation. The relevant amounts should be updated to ensure that the fees, charges and remuneration payable are adjusted for such inflation before the date of application of this 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 this 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.

Revision

The report 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.

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. 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.