Fees and charges payable to the European Medicines Agency

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

The European Parliament adopted by 562 votes to 35, with 6 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and 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 European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission's proposal as follows:

General objective

The general objective of this Regulation is to contribute to providing a sound financial basis for the operations of the Agency, thus contributing to ensuring a high level of protection of public and animal health. It should establish cost-based fees and charges to be levied by the Agency, as well as cost-based remuneration to competent authorities of the Member States for the services they provide for the completion of the Agency’s statutory tasks.

Medicinal products for human use which are authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC shall not be subject to the fees for pharmacovigilance activities set out in the Annexes to this Regulation.

Appropriate funding

The amended text points out that, following the COVID-19 pandemic and a rise in the number of initiatives in the field of health at Union level, the Agency is faced with a constantly increasing workload, which can entail additional budgetary needs in terms of staff and financial resources. The additional workload should be accompanied by appropriate funding to ensure, among other things, that the Agency can fulfil its obligations and transparency commitments.

Given that the Agency is a public authority, it is of utmost importance to safeguard its integrity and independence in order to maintain public trust in the Union regulatory framework.

Reductions and deferrals of fees and charges

Member States or Union institutions that have requested an assessment, opinion or a service from the Agency should not be subject to fees or charges under this Regulation.

On a reasoned 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 fee or charge. The Agency should make information on such reductions publicly available on its website, after deletion of all information of a commercially confidential nature.

Non-profit organisations and academia should also benefit from fee reductions provided that they are not owned or controlled by a commercial undertaking and that they have not concluded agreements with any commercial undertaking concerning sponsorship or participation in the development of the medicinal product which would give the commercial undertaking any rights to the final medicinal product.

Access to information

The general public should have access to information on the granting by the Agency of reductions or waivers of fees and charges and on the amounts of remuneration paid to competent authorities of the Member States, broken down by Member State and by activity. That information should not include, however, any commercially confidential information. The Agency should therefore remove such information in advance, where relevant.

Adjustments related to inflation

The amounts of the fees and charges of the Agency and of the remuneration to competent authorities of the Member States should be adjusted, where appropriate, to take account of significant changes in costs, detected through cost monitoring, and to take account of inflation.

According to the amended text, the first adjustment of fees, charges and remuneration due to inflation should take into account the annual inflation rates for each calendar year following the inflation adjustment already applied to the amounts in the Annexes, up to and including 2024. The inflation rate already applied to the amounts in the Annexes for 2023 is 5.9 %, which corresponds to the projected annual inflation for 2023, and 1.2 % for 2024. The first adjustment due to inflation should therefore also take into account the correction needed in view of the final annual inflation rate for 2023 and 2024.

Revision

Any revision of the fees and charges and of the remuneration paid to competent authorities of the Member States provided for in this Regulation should be based on the Commission's evaluation of the Agency’s costs and revenues and of the full costs of the services provided to the Agency within the scope of this Regulation by the competent authorities of the Member States, taking into account also the impact of such services on the sustainability of the operations of the Agency, including the services provided to the Agency by the competent authorities of the Member States, and a fair and objective allocation of fees, charges and remuneration.

The Commission may take into account any factors that could have a substantive impact on the Agency’s costs, including but not limited to the **workload** associated with its activities, and potential risks related to fluctuations in its fee revenue. The fees and charges should be set at a level which ensures that the Agency has sufficient revenue to cover the costs of the services delivered.

Annexes

The amended text revises the annexes concerning fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use and veterinary medicinal products.

In any revision of the Annexes, the amounts of remuneration paid to competent authorities of the Member States provided for in this Regulation should be maintained as a single amount of remuneration irrespective of the Member State of the competent authority concerned.