Fees and charges payable to the European Medicines Agency

2022/0417(COD) - 13/12/2022 - Legislative proposal

PURPOSE: to ensure appropriate funding of the European Medicines Agency (EMA) activities carried out at Union level.

PROPOSED ACT: Regulation of the European Union and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: the European Medicines Agency (EMA) plays a key role in ensuring that all medicinal products placed on the EU market are safe, effective and of high quality, thereby contributing to the proper functioning of the internal market while ensuring a high level of human and animal health protection. It is therefore necessary to ensure that it has sufficient resources to finance its activities, in particular from the fees it collects.

Over the years, the legal framework governing EMA fees has become rather complex, requiring some legislative simplification. When establishing a new fee system for veterinary medicinal products, the characteristics and specificities of the veterinary sector should be taken into account.

This revision also aims to **address the following problems** identified by the recent evaluation of the EMA fee system:

- complexity of the fee system due to the many different categories and types of fees it currently establishes;

- misalignment of some fees with underlying costs;

- lack of any fees or national competent authority remuneration for some procedural activities;

- misalignment with the underlying costs of certain remuneration paid to national competent authorities in Member States; and

- discrepancy between the main EMA Fee Regulation and the Pharmacovigilance Fee Regulation, which differ in their approach to determining the amount of national competent authority remuneration and in the approach to national competent authority remuneration in the case of reduced fees.

By addressing these specific problems, the general objective of this proposal is to **contribute to providing a sound financial basis to support the EMA's operations**, including remuneration for services to the EMA rendered by national competent authorities, in line with the applicable legislation.

The proposal also aims to: (i) **streamline the system by simplifying the fee structure** to the extent possible and by addressing the unnecessary complexity of the corresponding legal framework through bringing together in a single legal instrument fee rules that are currently governed by the two EMA Fees Regulations, (ii) **make the fee system future-proof** by introducing regulatory flexibility in the way it is adjusted, on an objective basis.

CONTENT: the general objective of this Regulation is to **contribute to providing a sound financial basis for the operations of the Agency** by establishing 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.

This Regulation lays down the following:

- the amounts of the fees and charges established on cost-based evaluation and **levied** by the European Medicines Agency (the 'Agency') for assessment activities relating to obtaining and maintaining a Union authorisation to market medicinal products for human use and veterinary medicinal products and for other services provided or tasks carried out by the Agency;

- the corresponding amounts of **remuneration** established on cost-based evaluation and payable by the Agency to the competent authorities of the Member States for the services provided by rapporteurs and, where applicable, co-rapporteurs from competent authorities of the Member States, or by other roles considered as equivalent for the purposes of this regulation, as referred to in the Annexes to this Regulation; and

- the **monitoring of costs of activities and services** provided by the Agency and of costs for remuneration.

In order to have a fair system, it is proposed to identify a **harmonised unit** by which relevant pharmacovigilance-related fees would be charged with regard to nationally authorised products.

The proposal:

- describes the types of fees and charges than can be levied by the EMA and refer to the relevant annexes where the corresponding amounts are laid down with, where relevant, the amounts for remuneration to the national competent authorities in Member States;

- deals with the conditions of remuneration paid to national competent authorities in relation to fees levied by the Agency;

- sets out applicable fee reductions and related rules and refers to the relevant annex where the reductions are set out: the EMA Executive Director is empowered to grant further fee reductions in exceptional circumstances, while the Management Board of the Agency is empowered, following a favourable opinion from the Commission, to grant further reductions in non-exceptional circumstances for justified reasons, such as for protection of public and animal health;

- concerns the conditions and rules pertaining to payment of fees and charges.

- mandates the Management Board of the Agency to specify detailed technical arrangements to facilitate the application of the proposed regulation;

- deals with due dates and provides for the possibility for the Executive Director to suspend services in the case of non-payment;

- sets out requirements for transparency of the amounts provided for by the proposed regulation and provides for monitoring of costs and inflation and reporting;

- sets out the conditions for a review of the amounts laid down in the Regulation, following a cost-based approach.

Lastly, it is proposed that the annexes to this regulation should be amendable by **delegated acts**. The annexes lay down the cases where a fee is charged and where remuneration is paid to national competent authorities, as well as the amounts of those fees and the amounts for national competent authorities' remuneration and the applicable fee reductions.