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European Medicines Agency: Council and Parliament strike deal on a sustainable and flexible fee system

The presidency of the Council and European Parliament negotiators reached a provisional agreement on a regulation to modernise and simplify the structure of fees payable to the European Medicines Agency (EMA). The agreement still needs to be confirmed by both institutions before going through the formal adoption procedure.

> Today's agreement marks the transition to a sustainable, simpler and more flexible fee system for the European Medicines Agency. In order to ensure safety and high-quality medicines in the Union market, it is of paramount importance to ensure adequate funding for the agency and national competent authorities to deliver a top-class regulatory system.
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> — José Manuel Miñones Conde, Spanish Acting Minister of Health

Facts and figures on the EMA's fees

The EMA charges a fee for processing applications from companies that wish to launch a medicine on the market, as well as for other tasks, such as monitoring the safety of medicines (pharmacovigilance). For 2023, fees and charges accounted for around 89% of the agency's budget.

The agency also pays national authorities for the scientific evaluation of applications. In 2023, it is estimated that €163 million will be paid to the national medicines regulatory agencies from the agency's budget.

Why does the EMA's fee structure need updating?

The EMA plays a crucial role in protecting and promoting human and animal health by evaluating and monitoring medicines. In order to deliver on its mission, the agency needs a sound financial basis to support its operations. However, the existing fee structure is increasingly complex and no longer reflects the nature of the work and the challenges involved.

Key elements of the provisional agreement

The provisionally agreed text stipulates that fees charged by the EMA should be cost-based. The text provides for a simplification of the current legal framework by establishing a single legal instrument for all fees (pharmacovigilance and marketing authorisations).

It also provides for a more sustainable and flexible fee system, which will ensure both adequate funding for the EMA and sufficient support for national competent authorities in their tasks. To this end, three changes were introduced in the initial proposal:

- adjustment of certain fees to reflect inflation rates, including medicines for human use, and a smaller increase for veterinary products
- increase of fees for scientific advice and procedures regarding generic medicines, in order to put EMA on a sustainable financial footing
- increase in remuneration allocated to national competent authorities in order to cover the full costs of the work that they do for EMA and to ensure that they have the necessary qualified staff to do so

The provisionally agreed text also contains changes to the monitoring and revision of fees. The aim is to increase the flexibility of the system and make it adaptable to future needs. In particular, the amendments are designed to expand the role of EMA's management board, covering such areas as the updating of fees or adapting these to changing circumstances.

Background

The EMA's existing fee system has been in place for almost two decades, during which time it has become increasingly complex. A recent evaluation of the system identified a series of key issues. These included the misalignment of some of the fees with the underlying costs, a lack of sufficient costing for certain procedural activities, the overall complexity and lack of flexibility of the system, and discrepancies between relevant legal provisions.

On 13 December 2022, the Commission published a proposal for a regulation revising the existing EMA fee system. The proposal has three objectives:

- to move from a flat-rate to a cost-based fee system
- to ensure the sustainability of the European regulatory network formed by the EMA and national competent authorities
- to simplify existing legislation by merging the content of the two current EMA fee regulations for pharmacovigilance and non-pharmacovigilance fees into one single legal instrument

Next steps

Today's provisional agreement must now be endorsed by the Council and the Parliament. It will then be formally adopted by both institutions. Negotiations between the two co-legislators were launched on 5 September and are concluded with today's agreement.

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