European Commission - Press release

European Health Union: Commission welcomes political agreement on the European Medicines Agency's fees

Brussels, 25 September 2023

The Commission welcomes the political agreement reached today between the European Parliament and the Council of the EU, on the Regulation on fees charged by the European Medicines Agency (EMA). The new rules, proposed by the Commission in December 2022, will ensure that these fees **better reflect EMA's work to assess the quality, safety and efficacy of medicines** before they are authorised in the EU, allowing the Agency to continue delivering scientific excellence in the evaluation and supervision of human and veterinary medicines. The fees will also better cover the important scientific contribution of the Member States' authorities to this process.

When companies request a marketing authorisation for a medicine, they pay a fee to EMA for the agency's rigorous scientific assessment. This fee includes the compensation that EMA pays to national authorities involved in the assessment process.

The agreement reached today will **streamline EMA's fee structure to ensure that the fees better reflect all associated costs** and are more **transparent** on the amounts paid to the national authorities. The new rules also introduce a **cost-monitoring mechanism** and the flexibility to adjust the fees in case of significant changes in the underlying costs. The specificities of the **veterinary pharmaceutical sector** are also taken into account by providing targeted fee reductions to support the availability of veterinary medicines.

Next steps

The political agreement reached by the European Parliament and the Council is now subject to formal approval by the two co-legislators. Once adopted, the Regulation will enter into force on the day following its publication in the Official Journal.

For More Information

European Medicines Agency's (EMA) fee system - Impact assessment and Commission proposal (europa.eu)

IP/23/4588

Quotes:

> I warmly welcome today's agreement between the European Parliament and the Council. These new rules will enable the Agency to collect fees that better reflect its crucial function of assessing the quality, safety and efficacy of medicines in the EU. It will also allow EMA to properly compensate national authorities for their scientific input. Today's agreement marks another advance in creating a strong, sustainable and resilient European Health Union, with a future-proof and flexible EMA capable of adapting to new challenges as one of its pillars.
> Stella Kyriakides, Commissioner for Health and Food Safety - 25/09/2023

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