

European Parliament lends its support to a fair cost-based approach on EMA fees

Brussels, 30 June 2023

The European Parliament ENVI committee has recognised the importance of a fair, cost-based approach for the EMA fee system in line with the European Court of Auditors. This comes together with a simpler fee structure, adequate financing and transparent evaluation of costs with the objective to provide equitable support to the EMA and the national competent authorities (NCAs) conducting assessments and other activities on behalf of EMA.

The cost-based approach is critical for generic and biosimilar medicines to keep regulatory fees at a reasonable level and to avoid the withdrawal of older, but essential, medicines from national markets. While the cost of regulatory processes may be irrelevant for high-profit-margin medicines, for generic medicines with very low margins, regulatory costs can be critical in maintaining older products or supplying products to small markets or markets with lower or even zero profitability. Recently published [data](#) shows that this over-consolidation of generic medicine supply is a serious risk for supply. Therefore, from a generic medicine perspective, fees must be reasonable, affordable and aligned with true costs for regulatory authorities as stipulated in the Parliament's position. We call on the Parliament to maintain a strong negotiating position and to reject the Council's across-the-board and unjustified 20% increase of regulatory fees and event 300% increase in pharmacovigilance fees in comparison to the current amount, that will fall mainly on low-cost generic medicines. The Council position is in blatant contradiction with the clear recommendations of the European Court of Auditors that fees should be cost-based and proportionate.

The off-patent medicines sector operates in a highly regulated market where medicine prices are capped by national pricing and reimbursement authorities at very low levels and are subject to automatic price reduction measures, known as reference pricing. Most Member States apply additional price reduction measures to our medicines in the form of price freezes, clawback measures, mandatory rebates, rebate contracts and non-negotiable price reductions. This combination of cost inflation, increasing regulatory costs, including EMA fees and price control policies threatens the availability of medicines and makes EU manufacturing unsustainable.

Beata Stepniewska Deputy Director General & Head of Regulatory Affairs at Medicines for Europe said *"fees should be fairly redistributed among EMA and NCAs to limit any high increase and to reflect time invested in the assessment of medicinal products. We call on the Parliament to strongly defend its position vis-à-vis the Council which is dramatically increasing costs for low margin generic medicines thereby threatening supply and availability of the most essential medicines. The financial burden on the generic industry will be disproportionately high with direct impacts on equitable access to medicines in Europe."*

DOCUMENT

Court of Auditors report: [here](#)

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information, please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.