



# Position Paper on fee system for regional joint assessment procedures in Africa

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Adequate and appropriate funding are essential to support the effective operation of the African Medicines Regulatory Harmonization (AMRH) program to ensure public health. In recent years, during the COVID-19 pandemic, society has been acutely reminded of the importance of a robust, resourced, efficient, and adaptable regulatory system.

The goal of having a strong regulatory system is to ensure that patients get access to medicines as quickly as possible, by operating regulatory assessment procedures in a predictable, streamlined, and most efficient way. This requires a fully integrated funding system throughout the lifecycle of a medicine that is built on **proportionality and fee-for-service**. **Such system should consider** regulatory activities for coordination of continental procedures under the African Medicines Agency, the coordination of regional Joint Assessment Procedures under regional secretariats and the assessment work carried out by the National Regulatory Medicine Agency (NMRAs)<sup>1</sup>.

## Industry perspective

IFPMA supports the implementation of a user fee system that is consistent with the fundamental principles of **transparency, equity and proportionality, sustainability, simplicity, and flexibility**.

- **Transparency:** The proposed fee structure should be based on a comprehensive, transparent and independent evaluation of the underlying costs of the services provided, projections of future developments and strengths and weaknesses of the current system.

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<sup>1</sup> Given its essential role in patient health, IFPMA considers that public monies should contribute a significant portion to achieving a well-resourced, robust African regulatory system, and many non-fee-generating activities and infrastructure investments should be supported by public budgets.

- **Equity and proportionality:** Fees must correspond to the service provided (i.e., “fee-for-service” principle) and should be equitable and proportionate for all parties involved whether they are local or international companies.
- **Sustainability:** To support public health and pharmaceutical innovation, the fee structure should ensure adequate availability of resources to support efficient and quality scientific assessment by fully dedicated and qualified experts within optimized timelines.
- **Simplicity:** The fee system should be clear and simple to avoid an unnecessary administrative burden for the payers of the fees and for the regulators collecting the fees.
- **Flexibility:** Reductions and waivers should be allowed for some procedures for certain justified categories of medicines and actors (e.g., orphan drugs and SMEs), or in exceptional circumstances (e.g., imperative reasons of public health).

Fees should be determined based on actual costings and linked to agreed regulatory performance indicators. A periodic performance re-assessment process of the operational functioning of the regulatory system should be implemented to establish a mechanism for justified fee adjustments<sup>2</sup>.

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<sup>2</sup> An example of such regular review linked to performance goals is the FDA Prescription Drug User Fee Act (PDUFA)