**EFPIA Position Paper on EMA Fees**

Adequate and appropriate funding of European Medicines Agency (EMA) and National Competent Authorities (NCAs) is essential to support the effective operation of the European Medicines Regulatory Network and to ensure public health. As such, EFPIA welcomes the ongoing evaluation of the current EMA fees system.

EFPIA members would support a revision of the current fee system provided that the following fundamental principles are met:

* **Transparency**: Changes to the 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.
* **Fairness & proportionality**: Fees must correspond to the service actually provided and should be fair and proportionate for all actors involved. While it is accepted that the majority of the EMA budget will continue to be derived from fees payable by Industry, some activities conducted by the Agency are part of its general mission to ensure public health and should therefore remain partly covered by the Community.
* **Sustainability**: In order to support public health and pharmaceutical innovation, the fee structure should ensure adequate availability of resources to support high quality scientific assessment by highly qualified experts within competitive timeframes.
* **Simplicity**: The fee system should be clear and simple in order to avoid unnecessary administrative burden for payers.
* **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).

In addition, EFPIA is mindful of the future needs of the network for a fee structure that facilitates initiatives on reduction in administrative burden being evaluated by the Regulatory Optimisation Group (ROG). To that end EFPIA would support changes to the Fees system that meet the above criteria but also enable simplification initiatives and remain cost-neutral overall to companies for the same volume of submissions, and provide EMA with the required income for their assessment work. The regulatory system resource savings from EFPIA’s proposal could then be redirected to essential initiatives such as implementation of the EMA’s Regulatory Science Strategy to 2025.

**Executive Summary**

**Introduction**

The current fee system seeks to levy fees from Marketing Authorisation Applicants and Marketing Authorisation Holders (MAH), in a proportionate way, with lower fees being charged for simpler procedures requiring minimal or no scientific review and higher fees being charged as complexity of scientific review increases, with the highest fees being charged for assessment of Marketing Authorisation Applications (MAAs) for new active substances.

Whilst Industry absolutely agrees with the principle of levying fees in a proportional way, implementation of the current fee structure has resulted in some anomalies in the way this is applied that need amendment. In addition, an unintended consequence of the way in which fees are charged has resulted in significant levels of resource being diverted to process and invoice the simplest administrative submissions, resource that could be better utilised by all stakeholders to advance innovation and patient health.

This position paper proposes a potential way forward to deal with the anomalies in the current fee system and a new way to deal with the simpler, resource consuming submissions whilst maintaining a cost-neutral funding model that ensures continuity of existing current funding levels for EMA.

**Proposal:**

1. **Expansion of the Scope of the Annual Maintenance Fee**

Whilst fee levels for Type IA, so called “do and tell” variations and Type IB variations are relatively low compared to other categories of procedures that attract a fee, these variations numerically comprise the majority of submissions made to EMA that attract a fee.

Whilst these variations are simple by definition, the numbers involved result in the need for significant resourcing levels at the Agency and at the MAH simply for processing and invoicing purposes, which seem disproportionate since minimal or no formal scientific review is required. A predictable and equitable fee structure which significantly reduces the administrative burden associated with their financial processing by companies and EMA, while generating the necessary level of income for the Agency, would benefit all.

In addition, the experience of EFPIA member companies suggest that the number of Type IA variations submitted per MA per annum decreases with time over the lifecycle of the medicinal product, regardless of the specific product or MAH.

Thus EFPIA’s proposal comprises:

* Replacement of Type IA and Type IB variation fees with an annual maintenance fee for all MAs, based on the xEVMPD database (at the formulation level):
  + The advantages of adoption of a single charge per MAH per MA per year are that the system would be much simpler and predictable to apply, for both the Agency and Industry. Furthermore it promotes streamlining of variation processes and procedures by removing the unintended incentive to classify more and more regulatory activities as variations to increase income from fees.
* The following types of procedures would be included in the expanded annual maintenance fee since they comprise routine maintenance activities for all MAs:
  + PV activities;
  + Renewals.
* Lower annual maintenance fees would be appropriate for products no longer subject to renewal to reflect the decreasing number of changes made to MAs during their lifecycle as products become more established. EFPIA proposes:
  + Implementation of a 3 Tier level maintenance fees system, with a decrease of maintenance fees after 5 years and a further decrease after 10 years to reflect the decreasing workload.
* MAAs authorized as true duplicates (identical Module 3, same indications) would be subject to the lower Tier III level maintenance fee throughout lifecycle to reflect the fact that no additional scientific review is needed compared to the original MA.
* The annual maintenance fee based system should be applicable to   
  Orphan Medicinal Products, Conditional MAs and Authorisations under Exceptional circumstances since they require similar levels of maintenance activities as other MAs.

The level of the maintenance fee per MA would be set to ensure introduction of the new fee system would be cost-neutral to EMA overall.

1. **Other Changes to Current Fee System for Type II Variations**

There are some unintended anomalies in the way in which the current fee system is applied which means that for some submissions, the level of fee charged is no longer proportional to the level of scientific review required. To address these anomalies the following are proposed:

* Differentiation between fee levels for different Type II variations to reflect the level of scientific review required. Lower fees may be applicable for:
  + some post-authorisation measures (PAMs) (e.g. by taking into account the volume of clinical data submitted);
  + adding a side effect (based on the level of scientific review) to the product information.
* Updated version of Module 3.2.5 or the Active Substance Master File (ASMF) to be submitted as a single Type II variation applicable to all medicinal products using that ASMF instead of a grouped variation application.

1. **Other Changes to Current System, if an Expanded Annual Maintenance fee cannot be adopted**

If adoption of an expanded annual maintenance fee is not possible, then some additional modifications to the current system are needed to eliminate additional anomalies. These comprise:

* The need for a “bulk transfer fee” covering bulk changes of Company name or administrative address following a merger or other corporate change applying across a MAH portfolio. Such a fee category would reduce the invoicing and payment burden associated with the hundreds of virtually identical purely administrative submissions needed when companies are involved in such changes.
* The need for a cap on the level of fees that can be charged for grouping of Type IA/IB so that fees do not exceed the fee for a single Type II variation.

**Conclusions:**

EFPIA considers that adequate funding of EMA and NCAs is essential to support the effective operation of the European Medicines Regulatory Network and to ensure public health. As such, EFPIA welcomes the ongoing evaluation of the current EMA fees system.

Overall, EFPIA would support changes to the fees system that would result in a fairer, more transparent system that is sustainable, simple and flexible that would be cost-neutral overall to companies for the same volume of submissions, and provide EMA with the same income as the current system for the same volume of assessment work.

The regulatory system resource savings from EFPIA’s proposal could then be redirected to essential initiatives such as implementation of the EMA’s Regulatory Science Strategy to 2025.

A key way to achieve this would be to introduce an expanded annual maintenance fee that includes all Type IA/IB variations together with additional changes to the rest of the fee structure to remove a number of anomalies that have developed over time.