|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| EFPIA Logo.png | Draft |  |  | Final | star.pngstar.png |
|  |  |  |  |  |

|  |
| --- |
| **Submission of EFPIA comments on the EU Commission’s Inception Impact Assessment for Revision of the EMA fee system** |
| **Author: EFPIA** star.png **Date: 15 October 2019** star.png **Version: Final** |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bloc4.png | Bloc5.png | Bloc1.png | Bloc6.png | star.png | **Response** | Bloc2.png | Bloc5.png | Bloc3.png | Bloc6.png |

| Inception Impact Assessment Section | EFPIA Comments |
| --- | --- |
| Introduction | EFPIA welcomes the opportunity to offer comment on the EU Commission’s Inception Impact Assessment (hereafter referenced as IIA[[1]](#footnote-1)). Within these comments, EFPIA provides preliminary input from the point of view of the innovative pharmaceutical industry in order to have the most positive impact on the continued development and regulation of human medicines[[2]](#footnote-2). EFPIA represents 40 research-intensive pharmaceutical companies committed to researching, developing and bringing new innovative medicines to patients in order to improve patients’ health and quality of life. EFPIA also includes direct membership of 36 national associations.  EFPIA’s comments summarise fundamental principles for an ideal, fit-for-purpose EU fee system, describe the challenges innate to the current fees approaches, identify potential solutions to alleviate these issues, and offer preliminary assessment of the Commission’s proposed options. Unquestionably, EFPIA considers that 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 and offers these comments as support for the Commission’s IIA and overall fee review activities. Along with the comments offered here in response to the Commission’s public consultation request, EFPIA is also pleased to share our full Position Paper on EMA Fees as an attachment. |
| A. Context, Problem definition and Subsidiarity Check | The EMA Founding and Fee Regulations[[3]](#footnote-3) noted a foundational intent for the EU fee system that “the structure of the fees should be as simple as possible to apply in order to minimise the related administrative burden”. EFPIA considers that the fee system has become increasingly complex over the years since its introduction. An unintended consequence of the way in which fees are charged is that significant levels of resource are 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.  EFPIA believes that efficiency improvements instituted to simplify the fee system would have a substantial positive effect on EMA, and on those paying fees, given the scale of its total budget (i.e., €337.8 million1), which accounts for around 90% of the Agency’s budget1.  One of the reasons that the Commission gives for necessitating a fee change is to “address changes to the rules applicable to the authorisation of veterinary medicinal products”1. EFPIA considers that any changes instituted in the near-term within the Fees Regulation to improve the fee system for human medicines should predict, and be flexible enough to accommodate, future advances in medicine development and subsequent adjustments to the Regulations.  Within the IIA, the Commission describes “weaknesses identified by the recent evaluation of the EMA fee system”1 in terms of its administration as well as remuneration levels for activities between the EMA and NCAs. EFPIA’s agree with the Commissions IIA conclusions: “(i) The fee system is complex due to many different categories and types of fees and therefore difficult to apply and not easily predictable. (ii) There is possible misalignment of some fees with the underlying costs.”1  As described in more detail in the attached full Position Paper on EMA Fees, EFPIA believes that fee system changes should adhere to the following principles:   * **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).   These principles are the lens through which EFPIA viewed the policy options presented by the Commission within the IIA. |
| B. Objectives and Policy option | **Policy Option 1 (baseline)**: *Limited changes to ensure financing the new/amended veterinary activities and to align the fee system to changes in the EMA Founding Regulation*1  **EFPIA assessment:**  EFPIA does not consider that Policy Option 1 would adequately address the challenges of the current system and would not introduce necessary improvements to the EU fee system for human medicines (“No modifications would be introduced to fees for human medicines under this option”1). Specifically, if implemented as a standalone change, Policy Option 1 would not address the weaknesses of complexity and possible misalignment of fees for human medicines as identified in the Commission’s analysis. EFPIA does not offer comment on the sub-options presented here and elsewhere within the IIA related to renumeration and distribution of budget between EMA and NCAs since this is a matter for agreement between the Agencies concerned.  **Policy Option 2: *A cost-based fee system for human and veterinary activities*** *with no changes to the fee system structure (with the exception of changes required by the new/amended veterinary activities and to align the fee system to changes in the EMA Founding Regulation, as per Option 1)*1  **EFPIA assessment:**  EFPIA considers that this option only partially addresses the deficiencies of the current system. Thus, Policy Option 2 seeks to align fees charged with “recently collected time and cost data”1. Without addressing how this cost-based fee assessment model would be calculated and changed over time with increasing efficiencies, however the concept seems allied with EFPIA’s principles of fairness, proportionality and transparency. Under Policy Option 2, the Commission explains that the “redefinition of main categories of fees and charges would be necessary”1. EFPIA concurs with this point, however, it is difficult to offer further detailed comment without knowledge of the proposed redefined fee categories.  Under Policy Option 2, the fee system would remain unduly complex and cumbersome for both the industry and Agency.  Additionally, Option 2 (and Policy Option 3 as commented on below) would introduce new fees for orphan and paediatric committee activities which currently do not involve fees. EFPIA does not believe that fees should be introduced for these activities as this proposal seems to be counter to the principle detailed in section B of “respecting fee incentives set in existing policies”1.  EFPIA note the absence of mention of fees for paediatric procedures in Article 47(3) of the paediatric regulation[[4]](#footnote-4). In the case of paediatric investigational plans (or PIPs), introducing fees for PIPs and for the subsequent modifications that are necessary during a PIP’s lifecycle would greatly exacerbate the existing administrative burden of the paediatric obligations.  EFPIA consider that new fees for orphan procedures would constitute a reduction in support of an incentive for industry and should be recognised as such. Further, the introduction of fees for these procedures would be in contrast with the original intent to foster development of medicinal products for orphan diseases. In the case of new fees for orphan product development, this might become a deterrent to seeking Scientific Advice.  Finally, since both areas apply to stages of drug development where outcomes remain highly uncertain, charging fees could, unintentionally, function as a disincentive for future engagement.  **Policy Option 3: *A cost-based fee system for human and veterinary activities, with a simpler and more efficient system structure****, taking into account also the changes required by the new/amended veterinary activities and the redefinition of fees/charges categories in the EMA Founding Regulation*1  **EFPIA assessment:**  EFPIA considers that Policy Option 3 is most consistent with its principles and position for improving the EMA fee system. EFPIA considers that the approach described would simplify many of the current complexities by introducing a “single CAP annual fee” for many procedures and variations. However, the precise details for implementing this proposal would need to be evaluated before EFPIA can provide its full support. For example, transparency would be required in order to confirm that such fees are proportionate to the Agency’s workload.  EFPIA concurs that a separate fee for licence extensions would appear justified. Simplification of pre-authorisation procedure fees is also welcome, although details regarding changes for product with PRIME designation need to be evaluated, again to ensure innovation is not discouraged.  EFPIA reiterates its concerns for levying fees for orphan and paediatric medicines as mentioned under Policy Option 2 above.  Finally, it remains unclear how the conserved Agency resources resulting from administrative simplification would be redirected to support other essential Agency missions such as implementation of the EMA’s Regulatory Science Strategy to 2025[[5]](#footnote-5).  **Summary of EFPIA assessment:**  In summary, EFPIA considers that Policy Option 3 appears to be most consistent with its principles and position, and therefore, holds the most promise. Specifically, EFPIA supports 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. EFPIA does not support the addition of fees for orphan and paediatric activities as they risk de-incentivising research in these areas of high un-met medical need in the future and run contrary to the Commission’s stated principle of respecting fee incentives set in existing policies. |
| C. Preliminary Assessment of Expected Impacts | **Economic Impacts:**  EFPIA concurs with the Commission’s assessment that “(r)ecalculating fees to reflect recently collected time and cost data would make them fairer, and bring them closer to the level of the costs”1. With cost-based analyses, fees should be recalculated at least annually based on the inflation rate, and the resulting assessment should be communicated for public consult. EFPIA also agrees that “(s)implification of the fee system could have a positive impact on financial predictability for fee payers, reduce the administrative burden for them and for EMA, and could reduce the impact of fluctuations of fee revenue on EMA’s budget”1,4.  **Social impacts:**  IIA states that a “fairer, simpler and more efficient fee system can positively affect EMA’s ability to carry out its activities in an effective way, in terms of timely and high-quality assessment of the quality, safety and efficacy of medicines, by reducing the administrative burden”1. EFPIA concurs with this assessment of the likely positive impact on EMA and similarly on the opportunity to also improve public health by enabling more efficient procedures and more timely access to new medicines. In fact, procedural and administrative efficiency gains from fee system changes may improve overall regulatory timelines[[6]](#footnote-6). |
| D. Evidence Base, Data collection and Better Regulation Instruments | EFPIA appreciates the opportunity to comment on the Inception Impact Assessment and offer input on the policy options. The Commission notes that the public consultation should be “launched by the end of 2019 and would run for a period of 12 weeks”1. EFPIA looks forward to continuing its engagement with the Commission and additional human medicine stakeholders during this upcoming consultation. With the fast-changing, state-of-art advances in medicine development and regulatory science, it is essential that the EU’s fee system remains transparent, fair and proportional, sustainable, simple and flexible in the future. |

1. Public Consultation: EU Commission, DG Santé, Inception Impact Assessment for Revision of the EMA fee system; September 2019. [↑](#footnote-ref-1)
2. EFPIA’s comments are in the context of fees levied within the EU Regulatory System for regulatory activities provided for human medicinal products. [↑](#footnote-ref-2)
3. Council Regulation (EC) No 297/95 and Regulation (EU) No 658/201 [↑](#footnote-ref-3)
4. *Article 47(3). Assessments of the following by the Paediatric Committee shall be free of charge: (a) applications for waiver; (b) applications for deferral; (c) paediatric investigation plans; (d) compliance with the agreed paediatric investigation plan.* [↑](#footnote-ref-4)
5. Responding to the public consultation on EMA Regulatory Science Strategy to 2025, EFPIA’s overall top three priorities from amongst EMA’s recommendations are: Foster innovation in clinical trials (Rec 2.2); Diversify and integrate the provision of regulatory advice along the development continuum (Rec. 1.7); and Promote use of high-quality real-world data (RWD) in decision making (Rec. 3.4). [↑](#footnote-ref-5)
6. Recent trend data demonstrate that EMA’s product review timelines are getting longer, and indeed, are notably longer compared with US (11). Centre for Innovation in Regulatory Science; R&D Briefing 70; New drug approvals in six major authorities 2009-2018: published 29 May 2019; http://www.cirsci.org/wpcontent/uploads/2019/05/CIRS-RD-Briefing-13052019\_for-send-out.pdf [accessed 30 May 2019] [↑](#footnote-ref-6)