**EFPIA’s Supplementary Comments: Impact assessment study for the EMA fee system**

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents 39 research-intensive pharmaceutical companies as well as membership of 36 national associations. EFPIA appreciates the opportunity to offer comment on the EU Commission’s Impact Assessment (IA) targeted questionnaire.

**Sound financial footing for EU regulatory system**

On 25th November 2020, the European Commission released its *Pharmaceutical Strategy for Europe[[1]](#footnote-1)* (EC Pharma Strategy). The EC Pharma Strategy notes that the “EMA fees system is key in funding regulatory activities at EU level and ensuring coverage of the relevant costs” and that the EC “will consider this in the upcoming revision of the EMA fee legislation”.

EFPIA considers that adequate and appropriate funding of the EMA (and National Competent Authorities) is essential to support the effective operation of the EU regulatory system and to ensure public health. In recent months, during the COVID-19 pandemic, society has been acutely reminded of the importance of a robust, resourced, efficient, and adaptable regulatory system. As such, EFPIA welcomes the ongoing evaluation of the current EMA fees system as part of the discussions to ensure that a suitably resourced EU regulatory system can fully support the innovative medicines of today and tomorrow. EFPIA’s members support a revision of the current fee system that is consistent with its fundamental principles of **transparency, fairness & proportionality, sustainability, simplicity, and flexibility.**

Some aspects of these principles seem well accommodated within the IA. However, EFPIA considers that the IA’s policy options may not go far enough to fully address the necessary improvements EFPIA had previously raised (e.g., administrative complexity, limited capacity to adapt to regulatory science innovations) for the EMA’s fee system. As an example, there do not appear to be provisions for reductions of fees for older products or duplicate licenses. Additionally, EFPIA does not believe that fees should be introduced for orphan and paediatric regulatory activities as new fees could be a disincentive to development. Finally, although we support a flexible and sustainable framework to progress the innovative use of data sources, EFPIA has important reservations with the proposed DARWIN EU funding approach.

**EFPIA prefers Option 3 “light” with important qualifications**

In considering the proposed options, EFPIA believes that Option 3 “light” is most aligned with its principles and those described by the Commission in its IA. Option 3 would introduce cost-based, justified, transparent, and validated calculation of fees and reduce the number of procedural fees by broadening the CAP annual fee. EFPIA considers that some of these proportionate and streamlined measures will assist in resource preservation, for regulators and companies, over the longer term. The regulatory system resource savings from implementing Option 3 could then be redirected to other future proofing initiatives such as implementation of some elements of the EMA’s Regulatory Science Strategy to 2025 (RSS)[[2]](#footnote-2) and funding for infrastructure improvements (e.g., DARWIN EU). In EFPIA’s opinion, the efficiencies gained from a broader CAP annual fee along with validated cost-based fees calculations could ultimately support swifter regulatory procedural timelines.

However, EFPIA believes that the introduction of fees for orphan and paediatric regulatory activities would be in contradiction with the original intent to foster development of medicinal products for paediatric and orphan diseases: such new fees would diminish incentives – in the broad sense of the term – for medicine developers compared with existing policies. EFPIA does not support the addition of fees for orphan and paediatric activities as fees would risk dis-incentivising research in these areas of high unmet medical need in the future.

Further, EFPIA has significant reservations with the funding proposals for DARWIN EU. Currently, there is no clear provision for direct industry interaction with DARWIN EU. Therefore, the proposal for industry fees to cover DARWIN EU maintenance costs from 2024 will be seen as a new ‘tax’ since the fee remitter would not experience the benefits of direct access to and analysis using the resource for which it is being asked to pay – a departure from the longstanding “fee-for-service” EMA fees principle. Additionally, within the DARWIN EU funding proposal, there are no detailed timelines or guarantees on the delivery for a usable network[[3]](#footnote-3), expectations for long-term (i.e., 2027+) costs, method for covering any unanticipated cost overruns (which is important since Option 3 would introduce cost-based fees calculations), or approach to fund any future network expansion. Presumably the scope of the analyses to be performed would include only post-marketing analyses since fees would be generated from CAP and pharmacovigilance procedures. Furthermore, the measures for, and transparency of, progress towards establishing DARWIN EU are currently unclear.

Finally, EFPIA considers that Option 3 may not fully address measures to improve the EMA’s fee system today while critically future proofing[[4]](#footnote-4) it for tomorrow. For example, there are no details on how EMA will resource its RSS agenda, new organisational construct, digitisation strategy, develop capacities and expertise to support advances in scientific fields, or engage in ongoing dialogue with fees remitters to introduce fees system improvements over time.

**EFPIA willing to discuss potential new funding models**

EFPIA is willing to consider other changes to the Fees system that meet its principles (including proportionality and fee-for-service) and that could provide EMA with financial resources to enact several medicine development recommendations from its RSS. Specifically, EFPIA is willing to discuss with the Commission and EMA fees stakeholders potential funding models in the regulatory science areas of PRIME, iterative R&D dialogue, and dynamic regulatory assessment, to ensure availability of the additional regulator resource needed to support these processes. EFPIA considers that such models, if implemented, should (as with all other activities) also be gauged by ongoing measures of impact as per the transparency principle.

In summary, EFPIA would appreciate the opportunity to discuss and further explore our qualified support of IA Option 3 “light” provisions including reservations with new paediatric and orphan product regulatory fees and for the proposed DARWIN EU funding model. EFPIA would also appreciate the opportunity to explore with the Commission potential new funding approaches for PRIME, iterative R&D dialogue, and dynamic regulatory assessment to future proof the EU regulatory system in support of delivering innovative medicines for patients.

1. European Commission Pharmaceutical Strategy for Europe; Brussels, 25.11.2020; COM(2020) 761 final. [↑](#footnote-ref-1)
2. https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-strategy#regulatory-science-strategy-to-2025-section [↑](#footnote-ref-2)
3. EFPIA is mindful of the ongoing, extended development timelines for the Clinical Trials Information System (CTIS) implemented as per the EU’s Clinical Trial Regulation (Regulation (EU) No 536/2014). [↑](#footnote-ref-3)
4. It is challenging to consider and offer support for an EMA Fees Option in advance of potential changes that may be introduced to the underlying pharmaceutical legislation. [↑](#footnote-ref-4)