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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	13 December 2022
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
Subject:	REGULATORY SCRUTINY BOARD OPINION - Impact assessment *- Proposal for an EP and Council Regulation on fees charged by the European Medicines Agency (EMA)*

Delegations will find attached document SEC(2022) 440 final.

Encl.: SEC(2022) 440 final

ANNEX

EUROPEAN COMMISSION

Brussels, 13.05.2022

SEC(2022) 440 final

REGULATORY SCRUTINY BOARD OPINION

Impact assessment

Proposal for an EP and Council Regulation on fees charged by the European Medicines Agency (EMA)

{COM(2022) 721 final}

{SWD(2022) 413 final}

{SWD(2022) 414 final}

{SWD(2022) 415 final}

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB

Opinion

Title: Impact assessment / Revision of EMA fees

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

All medicinal products within the European Union for human and veterinary use must be authorised based on the scientific assessment of their quality, safety and efficacy. The authorisation is delivered by the European Medicines Agency (EMA), with the involvement of Member States' National Competent Authorities (NCAs). EMA charges fees to marketing authorisation holders and applicants for obtaining and maintaining Union-wide marketing authorisations, and remunerates the NCAs for undertaking relevant assessment activities.

The scope of this initiative builds on the findings from 2019 Evaluation of the European Medicines Agency's fee system. This highlighted discrepancies between fees (including remuneration to NCAs) and underlying calculated costs. In addition, there is a need to align the fee system to recent legislation, in particular the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6). The fee and remuneration system of EMA is laid down in Council Regulation (EC) No 297/95 (main fee regulation) and Regulation (EU) No 658/2014 (pharmacovigilance fee regulation). The revision of the EMA fees is linked to the parallel revision of the overarching Union pharmaceutical legilslation, including the founding regulation of EMA (Regulation (EC) No 726/2004).

This opinion concerns a draft impact assessment which may differ from the final version.

(B) Summary of findings

The Board notes the additional information provided in advance of the meeting and commitments to make changes to the report.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

(1) The report does not sufficiently explain how this initiative interlinks with the revision of the EMA founding regulation and how synergies and complementarities will be ensured.

(2) The definition of what a 'cost-based system' is unclear. The report does not clarify to what extent the current system and its key elements is cost-based and what the potential for cost-effiency enhancing measures is.

(3) The report does not sufficiently analyse how the proposed changes impact fee payers.

(C) What to improve

(1) The report should explain in more detail the interlinkages and coherence with the upcoming revision of the EMA founding regulation. The report should clearly describe how the proposed fee system will be able to account for and adapt to changes in the founding regulation and how synergies and complementarities will be maximised.

(2) When presentating the problem, the report should give a more precise picture of what 'cost-based' entails. It should define the concepts of 'cost-based' and 'cost-reflectivity' and should better outline whether the current fees and remunerations are sufficiently 'cost-based'. For instance, it should assess to what extent the industry annual fees are charged on the principle of service actually provided to fee payers. The report should also better present the background of the cost alignment objective, and it should explain the trade-offs and the basis for the relative weight between cost alignment, simplicity and the flexibility objectives.

(3) The report should better explain the overall functioning and efficiency of the current system. It should better present how the NCAs are assigned to their tasks and what kind of process will be followed to ensure excellence in service and cost-efficiency. It should explain why internal efficiency improvement measures (possibly in interaction with the changes to the founding regulation) have not been considered to tackle the financial sustainability challenge. In this context, the report should clarify to what extent the current EMA and NCA services provision can be considered as overall performing well and cost-efficient.

(4) The report should better substantiate why country coefficients for NCAs would lead to to significant administrative burden and clarify whether the burden outweighs the benefits. It should assess the risk that the current NCA remuneration system overall may result in delivering the NCA services at the cost of the most cost expensive national authorities.

(5) The report should better describe why the baseline is not a viable way forward, in particular given the apparent lack of stakeholder support for the options presented. The report should outline the drivers behind the negative financial balance and explain why it is not possible to balance incomes and expenditures in the baseline scenario.

(6) The report should clarify the impacts on fee payers. It should explain better how the recalculation results in higher total industry fees. It should assess the consequences of the raising the costs for fees payers, such as impacts on innovation or on the number of new applications. In particular, the report should specifically account for consequences on fee payers from the veterinary medicine sector. It should also better reflect the views of fee payers from the various consultation activities.

(7) The report should better reflect the overall impact of this initiative on the development and availability of safe, effective, and quality medicines. It should also indicate if there are any significant social, environmental or fundamental rights impacts.

The Board notes the estimated costs and benefits of the preferred option(s) in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Proposal for an EP and Council Regulation on fees charged by the European Medicines Agency (EMA), including remuneration paid to National Competent Authorities (NCAs), for activities related to obtaining and maintaining marketing authorisations for medicinal products for human and veterinary use.
Reference number	PLAN/2018/4193
Submitted to RSB on	13 April 2022
Date of RSB meeting	11 May 2022

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

1. **Summary of costs and benefits**

Based on a benchmark approach[1], it can be estimated that an EU-average value for administrative cost per invoice is 60€ (or 35€ per fee). On that basis, the aggregate administrative costs and benefits for fee payers (mainly industry) can be estimated as follows:

Overview of costs – Baseline			
		Businesses (payers of EMA fees)	
		One-off	Recurrent
Payment of EMA invoices	Aggregate administrative costs	n.a.	€1,105,200 -€1,153,845[2] (depending on whether yearly administrative cost is estimated based on frequency of invoices or of unitary fees)

Overview of costs – Preferred option(s)			
		Businesses (payers of EMA fees)	
		One-off	Recurrent
Payment of EMA invoices	Aggregate administrative costs	n.a.	€1,041,495 -€1,050,240[idem] (depending on whether yearly administrative cost is estimated based on frequency of invoices or of unitary fees)

Overview of Savings (total for all provisions) – Preferred Option(s)			
		Businesses (payers of EMA fees)	
		One-off	Recurrent
Payment of EMA invoices	Aggregate administrative costs	n.a.	€54,960 -€112,350[idem] (depending on whether yearly administrative cost is estimated based on frequency of invoices or of unitary fees)

The weight of payments processed by SMEs is estimated, based on historic EMA data, at 13% of all payments. This means that 13% of the estimated on administrative costs and respective savings affect payers of EMA fees that are SMEs .

[1] EMA administrative invoicing costs scaled to an average estimated level used as a benchmark for EU administrative invoice processing cost for the EU. The EMA administrative invoicing costs stem from EMA own calculations.

[2] Estimation based on frequency (number of unitary fees or number of invoices) multiplied by unitary costs, both reported above. Same logic applied in the tables bleow.

Overall, based on the estimated overview of benefits in the table above (i.e. reduced administrative cost related to the preferred option) it can be concluded that the effect of the proposal on administrative costs of businesses is neutral (or slightly positive).