Council of the European Union

Brussels, 15 December 2022
(OR. en)

16076/22
ADD 1

Interinstitutional File:
2022/0417(COD)

PHARM 192
SAN 664
MI 950
COMPET 1041
IA 226
CODEC 2032

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
No. Cion doc.:	SWD(2022) 415 final
Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council

Delegations will find attached document SWD(2022) 415 final.

Encl.: SWD(2022) 415 final

EUROPEAN
COMMISSION

Brussels, 13.12.2022
SWD(2022) 415 final

COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council

{COM(2022) 721 final} - {SEC(2022) 440 final} - {SWD(2022) 413 final} - {SWD(2022) 414 final}

Introduction

Within the European Union (EU), all medicinal products for human and veterinary use must be authorised either at EU (central) or Member State (national) level. At EU level, the Commission authorises these products based on the scientific assessment of their quality, safety and efficacy, as delivered by the European Medicines Agency (EMA), with the contribution of national competent authorities (NCAs) in Member States. The EMA charges fees to marketing authorisation holders and applicants for obtaining and maintaining EU-wide marketing authorisations for medicinal products for human and veterinary use. The EMA remunerates NCAs for their scientific assessment work. The services for which EMA charges fees include scientific advice, assessment of applications for a marketing authorisation, changes to existing marketing authorisations (variations and extensions), and other pre- and post-authorisation procedures, and annual fees for the maintenance of already authorised medicines. Pharmacovigilance activities conducted at EU level for nationally authorised medicines for human use are also financed by fees paid by marketing authorisation holders to the EMA.

The legislation requires that EMA fees be based on an evaluation of the Agency's costs and of the related costs of services provided by Member States (national competent authorities).

The main problems facing the EMA fee system

The main problems, identified in the 2019 evaluation of the EMA fee system, are as follows:

- misalignment of some fees with the underlying costs of the activities estimated by the evaluation;
- misalignment of some NCA remuneration with the underlying costs estimated by the evaluation;
- the fee system may not be flexible enough to keep pace with innovations, meaning that, in the future, some assessment processes for new medicinal products will likely be more complex than in the past; and
- the fee system is rather complex and not fully coherent both externally with the underlying pharmaceutical legislation and internally between the two EMA Fee Regulations[1], thus creating unnecessary administrative burden and difficulties for some stakeholders when predicting the fees that will be charged.

These problems are driven by:

- new and amended procedures for veterinary medicines introduced as a result of revisions to the Veterinary Medicinal Products (VMP) Regulation[2]; and a new EMA

[1] Council Regulation (EC) No 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products and Regulation (EU) No 658/2014 of the European Parliament and of the Council on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use.

[2] Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC.

activity included in Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, which requires additional funds as of 2024[3];
- levels of fees and remuneration that are not fully cost-based on the granular level (i.e. unitary fees and unitary remunerations);
- lack of a clear approach to the distribution of the financial burden of fee incentives between the EMA and NCAs;
- lack of a monitoring system to track and detect significant trends having an impact on the cost base of fee and remuneration amounts, e.g. changes in complexity of scientific assessments;
- the wide variety of EMA activities and the complexity of the underlying pharmaceutical legislation; and
- lack of an appropriate mechanism to easily adjust the fee system to changes in EMA responsibilities (the full ordinary legislative procedure is required to amend the fee amounts set in the legislation beyond inflation adjustments).

These problems are a challenge to the financial sustainability of the EMA going forward, including the capacity of the Agency to remunerate NCAs for their contributions to EMA activities in line with the pharmaceutical legislation.

The case for and objectives of EU action

The general objective pursued is to provide the EMA with a sound financial basis for the future. The EMA is a decentralised Agency of the EU. The terms of its funding, including fees as a source of revenue, are determined exclusively by EU legislation. Any amendment of the two EMA Fee Regulations requires an ordinary legislative procedure. Hence, only the EU can act to enable the Agency to charge fees.

The specific objectives of the revision of the EMA fee system are to:

- align revenue from fees with estimated costs;
- align the EMA fee system with the VMP regulation;
- ensure a fair distribution of cost-based fees and cost-based NCA remuneration, while respecting applicable fee incentives; and
- achieve a balance between simplification of the system and a cost-based approach.

Options

This impact assessment analysed several policy options together with a number of horizontal measures and compared them with a 'do-the-minimum' scenario describing what would likely happen in the absence of legal action to update the EMA fee legislation.

[3] Financial statement of the Commission proposal, COM/2020/725 final, Specific objective No 3 '*Allow timely access and analysis of EU-wide health data to support better decision-making throughout the product lifecycle on medicines (development, authorisation, performance monitoring) with valid and reliable real-world evidence.'*

- Option 1 – align the fee system with the VMP regulation only, with cost-based fees for all veterinary medicine procedures as per the new VMP Regulation. Unchanged fees for human medicines.
- Option 2 – revise the entire EMA fee system with a cost-based principle being used to set all fees and all NCA remuneration rates for both veterinary and human medicine activities.
- Option 3 – same as Option 2, except that the fee system is simplified by including the cost of the majority of post-authorisation procedures under the annual fees (as opposed to charging a fee as the procedure occurs, as in Option 2).
- Option 3 Light – same as Option 3, however, with only partial simplification of the fee system structure by including in the annual fee the cost of only minor post-authorisation procedures (other procedures continue to attract a per-procedure fee).

The horizontal measures, considered for all four of these policy options, include:

- various combinations of general fee reductions and/or specific incentives for veterinary medicine fees, designed in line with the objectives of the VMP Regulation;
- the possible use of country coefficients to adjust NCA remuneration; and
- the possible allocation from the EMA to NCAs of some of the financial burden of fee incentives (i.e. the loss of fee revenues they imply).

All four options are cost-reflective, i.e. based on estimated respective average costs(options 2, 3 and 3 Light are cost-reflective for both the human and the veterinary sectors).

Conclusions

Options 2, 3 and 3 Light enable the EMA to cover on aggregate its costs, including for remuneration of contributions of NCAs. Of these, Option 3 Light is assessed as overall the most efficient option. Its implementation would be combined with targeted fee reductions for veterinary fees in line with the objectives of the VMP regulation, no application of country coefficients to modulate NCA remuneration, and no sharing with NCAs of the cost of fee reductions (i.e. EMA budget to cover that cost). It achieves balance between the objective of a cost-based fee system and the objective of simplification of the fee system. Both 'do-the-minimum' scenario and Option 1 were dismissed, as they would result in a deficit for the EMA budget, given the cost estimations made for the impact assessment, and taking into account the EU budget contribution to the EMA budget under the current multiannual financial framework.

The administrative burden generated by the fee system on payers, including SMEs and microenterprises, NCAs and the EMA, would not vary significantly between Options 1 and 2. Options 3 and 3 Light are, however, simpler and so imply a slightly reduced administrative burden.

None of the options would provide complete predictability of fees due from payers, but Options 3 and 3 Light would go further in addressing this issue than would Options 1 and 2. SMEs are eligible for fee incentives from the EMA (fee reductions, exemptions and/or

deferrals) under Commission Regulation (EC) No 2049/2005 (the SME Regulation). Incentives for SMEs remain applicable in all policy options and sub-options. Relative to Option 1, the other policy options imply slightly higher fee payments (net of incentives) by SMEs. However, further reductions granted, within the system, would compensate for that impact.

Also proposed is an effective and proportionate monitoring and evaluation framework. This would support future changes in the EMA fee system by providing a factual basis for adjustment of fees and remuneration. Flexibility of the fee system could be achieved by delegating some powers to the Commission to adjust the fee system, based on evidence generated by the monitoring system.